

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 - - -

5
6 IN RE: NATIONAL : HON. DAN A.
7 PRESCRIPTION OPIATE : POLSTER
8 LITIGATION :
9 :
10 APPLIES TO ALL CASES : NO.
11 : 1:17-MD-2804
12 :

13 - HIGHLY CONFIDENTIAL -

14 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

15 - - -

16 April 29, 2019

17 - - -

18 Videotaped deposition of
19 KATHERINE KEYES, Ph.D., taken pursuant to
20 notice, was held at the law offices of
21 Lief Cabraser, LLP, 250 Hudson Street,
22 New York, New York beginning at 9:08
23 a.m., on the above date, before Michelle
24 L. Gray, a Registered Professional
25 Reporter, Certified Shorthand Reporter,
26 Certified Realtime Reporter, and Notary
27 Public.

28 - - -

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15 VIDEO TECHNICIAN:

16 Henry Marte

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I N D E X
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Testimony of:

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None.	

1 THE VIDEOGRAPHER: We are
2 now on the record. My name is
3 Henry Marte, I am a videographer
4 with Golkow Litigation Services.

5 Today's date is April 29,
6 2019. And the time is 9:08 a.m.

7 This videotaped deposition
8 is being held at 250 Hudson
9 Street, New York, New York, in the
10 matter of National Prescription
11 opiate litigation.

12 The deponent today is
13 Dr. Katherine Keyes.

14 All appearances are noted on
15 the stenographic record.

16 The court reporter please
17 administer the oath to the
18 witness.

19 - - -

20 ... KATHERINE KEYES, Ph.D.,
21 having been first duly sworn, was
22 examined and testified as follows:

23 - - -

24 EXAMINATION

1

- - -

2 BY MR. HERMAN:

3 Q. Professor Keyes, my name is
4 Steve Herman, I represent CVS Rx Services
5 Incorporated and CVS Indiana LLC. I
6 introduced myself briefly to you before
7 we got started, but nice to meet you on
8 the record?

9 A. Nice to meet you.

10 Q. Professor Keyes, you
11 understand that you're testifying under
12 oath today and that you're sworn to tell
13 the truth?

14 A. Yes.

15 Q. Great. Before we get going,
16 I just thought it would be good to go
17 over some sort of the rules of the road
18 here.

19 A. Okay.

20 Q. And as we're doing right
21 now, I'll ask you questions and I'll
22 expect you to answer truthfully and
23 completely. Okay?

24 A. Yes.

1 Q. Okay. Any reason you can
2 think of that you won't be able to answer
3 my question fully and accurately today?

4 A. No.

5 Q. As you know there's a court
6 reporter here, she's going to be taking
7 down everything we say. So if you could
8 answer audibly, saying yes and no rather
9 than mm-hmm or nodding your head. Do
10 you -- do you understand?

11 A. Yes.

12 Q. Great. Perfect.

13 And as we're doing well
14 right now I think, we'll take turns
15 speaking and I'll ask my question and
16 hopefully you'll wait and then I'll wait
17 for you to finish your answer?

18 A. Yes.

19 Q. And from time to time your
20 counsel, who I take it is sitting next to
21 you, may object, but unless your counsel
22 instructs you not to answer, you're
23 obligated to answer the question once
24 your counsel has made an objection on the

1 record. Okay?

2 A. Okay.

3 Q. And if you don't understand
4 one of my questions, please just let me
5 know and I'll try to rephrase it so you
6 can understand the question I'm asking.

7 A. Okay.

8 Q. And if I ask a question and
9 you give an answer, I'll take that as you
10 understanding my question.

11 A. Okay.

12 Q. And if at any time you need
13 a break, let me know and once we're done
14 with the question that's pending, we'll
15 try to take a break.

16 A. I apologize in advance, I
17 have a cold, so if you don't understand
18 any of my responses I'll try to repeat
19 it.

20 Q. Okay. Appreciate that.
21 It's that time of year when the weather
22 changes.

23 A. Yes.

24 Q. Professor Keyes, have -- the

1 materials that were provided with your
2 expert report say you've never testified
3 as expert at trial or by deposition in
4 the previous five -- four years; is that
5 correct?

6 A. That's correct.

7 Q. Prior to this case have you
8 been hired to serve as an expert in
9 connection with any litigation?

10 A. No.

11 Q. Okay. What did you do to
12 prepare for this deposition?

13 A. I wrote my expert report and
14 subsequent to that I reviewed it with the
15 attorneys.

16 Q. And did you meet with your
17 attorneys? When you say you reviewed it
18 with your attorneys, did you meet with
19 your attorneys to review your expert
20 report?

21 A. Yes.

22 Q. Okay. And how many times
23 did you meet with your attorneys?

24 A. Probably three to -- three

1 times, around.

2 Q. Okay. And do you recall
3 when the first time was?

4 A. After writing the report?

5 Q. The first time you met with
6 your attorneys after writing the report
7 to prepare for this deposition.

8 A. I don't recall the date
9 specifically. But it was, you know,
10 some -- sometime in the last month.

11 Q. Okay. And about how long
12 did you meet with your attorneys that
13 first time?

14 A. About two to three hours.
15 Three hours.

16 Q. And when you -- and who was
17 present at that meeting?

18 A. Joe was present. Ann
19 Ritter. Don Arbitblit was on the phone.
20 There might have been several others.

21 Q. And besides reviewing your
22 expert report, did you look at any other
23 documents at that meeting?

24 A. There -- there have been

1 several documents that, you know, that
2 have been circulated, that I think have
3 been filed with amendments that I've
4 looked at. But nothing other than what's
5 been disclosed. There were several other
6 documents. New -- new papers that came
7 out, things like that.

8 Q. Do you recall what those
9 papers were?

10 A. I think that they've been --
11 there was I think a New England Journal
12 article that was --

13 Q. Okay. Are you thinking --

14 A. -- came out subsequent to
15 the filing of the report.

16 Q. Okay. The two New England
17 Journal articles that were disclosed as
18 additional materials --

19 A. Yes.

20 Q. -- that you considered?

21 A. Yes.

22 Q. And you -- that was at the
23 first meeting.

24 At the second meeting, how

1 long did you meet with your attorneys?

2 A. Probably about the same,
3 three hours. Two to three hours.

4 Q. And same group of attorneys?

5 A. No. Ellen was there. And
6 Paula was there at that second meeting.
7 And several others, maybe.

8 Q. And besides your report, did
9 you look at any other documents at that
10 meeting?

11 A. I don't think at that
12 meeting I looked at other documents.

13 Q. Okay. And at --

14 A. Well, there were several
15 depositions related to, that -- that
16 Paula had sent me after that meeting,
17 from Summit and Cuyahoga County
18 testimony.

19 Q. Okay. Are those additional
20 depositions that were disclosed on the
21 supplemental list of --

22 A. Yes.

23 Q. -- materials considered?

24 A. Yes.

1 Q. And at the third meeting,
2 how long was that third meeting?

3 A. About the same, maybe three
4 to four hours at that point.

5 Q. And do you recall when that
6 meeting was?

7 A. That was yesterday.

8 Q. And besides your expert
9 report, did you review any other
10 documents at that meeting?

11 A. No.

12 Q. And which attorneys were
13 present at that meeting?

14 A. Ellen, Paula. Joe was on
15 the phone. Don was on the phone.

16 Q. Besides those meetings, did
17 you have any phone calls to prepare for
18 your deposition?

19 A. I've had --

20 MS. RELKIN: You can answer.

21 THE WITNESS: I've had
22 several phone -- I mean early --
23 just kind of to set up the
24 meetings I guess, with Ann and --

1 and Don Arbitblit. But not of any
2 substantial length.

3 BY MR. HERMAN:

4 Q. They were logistical
5 meetings, not substantive? Or logistical
6 phone calls and not --

7 A. I would consider them as
8 such.

9 Q. Okay. And you didn't
10 discuss substance during those calls?

11 A. There might have been
12 several, you know, small substantive
13 points that were discussed. I don't want
14 to say categorically that no substance
15 was discussed. But they were not
16 substantive preparational meetings.

17 Q. Okay. And besides those
18 three meetings where you prepared with
19 your attorneys, did you speak with anyone
20 else in preparation for your deposition?

21 A. No.

22 Q. Did you review any expert
23 reports?

24 A. I reviewed the -- well, they

1 are not -- I reviewed the depositions
2 that were sent to me.

3 Q. Okay. And those were sent
4 to you by -- who did you say?

5 A. Paula.

6 Q. Paula.

7 And besides what we've
8 discussed, the review of your expert
9 report, the review of the depositions,
10 and the review of those two New England
11 Journal of Medicine articles, did you do
12 anything else to prepare for this
13 deposition?

14 A. I reviewed my report and,
15 that's -- I think that is the summary of
16 it.

17 Q. Professor Keyes, when did
18 you first become aware of the opioid
19 litigation?

20 A. When did I first become
21 aware of the -- of which opioid
22 litigation?

23 Q. Well, when did -- let me ask
24 a different question. How did you come

1 to be retained in this case as an expert?

2 A. I was retained in December
3 of 2018 by Ann Ritter's office.

4 Q. And was Ann Ritter's office
5 the first person to reach out to you?

6 A. I had been in communication
7 prior to that with Paul Farrell, who I
8 did some consulting work for.

9 Q. And what was the nature of
10 the consulting work that you did --

11 MS. RELKIN: Objection.

12 BY MR. HERMAN:

13 Q. -- for Paul Farrell?

14 MS. RELKIN: Objection.

15 It's consulting work. It's not
16 related to her report.

17 BY MR. HERMAN:

18 Q. You can answer it.

19 MS. RELKIN: I'm going to
20 instruct you not to answer.

21 BY MR. HERMAN:

22 Q. Okay. Are you going to take
23 your counsel's instruction?

24 A. Yes.

1 MR. SHKOLNIK: On behalf of
2 Cuyahoga County, I'll note an
3 objection. This witness is not
4 represented by any of the
5 plaintiffs' attorneys here, and
6 you keep saying "your attorneys".
7 If you're referring to the MDL
8 attorneys or Cuyahoga's attorneys,
9 please so state that.

10 That's my objection for the
11 record going forward.

12 BY MR. HERMAN:

13 Q. Professor Keyes, are you
14 represented by any attorneys here?

15 A. I don't know what that
16 means. Can you -- can you give me a
17 definition of what that means?

18 Q. Who retained you to serve as
19 an expert in this case?

20 A. Ann Ritter's office.

21 Q. Okay. And you were retained
22 to serve as an expert in -- for Cuyahoga
23 County?

24 A. I was -- I was retained for

1 this case. I don't know if it was
2 specific to a county, one county or the
3 other. It was for the case.

4 Q. Do you understand that this
5 case is -- the two cases at issue in
6 Track 1 are Cuyahoga County and Summit
7 County?

8 A. Yes, I understand that.

9 Q. Okay. And you're serving as
10 an expert for Cuyahoga County?

11 A. I'm serving as an expert
12 for -- I was -- my report covers both
13 counties.

14 Q. At the time that you
15 accepted the engagement, what did you
16 understand your responsibilities to be?

17 A. To write an expert report, a
18 Track 1 report, regarding a number of
19 different issues related to the
20 epidemiology of opioid use disorders and
21 overdose with regard to the opioid
22 epidemic.

23 Q. And were you given specific
24 topics to cover?

1 A. Yeah.

2 Q. What were those topics?

3 A. They're covered in the
4 report. They ranged from kind of the
5 scope of the problem of the opioid
6 epidemic, the opioid use disorder, kind
7 of more accurate estimates of opioid use
8 disorders following medical use and what
9 had previously been reported in some of
10 the materials from defendants, the
11 connection between opioid -- prescription
12 opioid use and heroin use, different
13 abatement policies, different abatement
14 plans that have efficacy in the
15 epidemiological literature, the burden of
16 overdose in Summit and Cuyahoga County,
17 neonatal abstinence syndrome in the two
18 counties, as well as nationally, as well
19 as a range of other issues.

20 Q. You mentioned that you were
21 assigned to come up with more accurate
22 estimates of opioid use disorder. Did
23 you understand that to be your
24 assignment?

1 MS. RELKIN: Objection to
2 form.

3 THE WITNESS: So what I
4 reviewed, to be more specific, was
5 the evidence regarding opioid use
6 disorder following medical use of
7 opioids in the literature.

8 BY MR. HERMAN:

9 Q. Okay. And were you asked to
10 come up with a more accurate estimate?

11 A. I was asked to review the
12 literature.

13 MS. RELKIN: Objection.

14 BY MR. HERMAN:

15 Q. How much time have you spent
16 working on this case to date?

17 A. I don't know the specific --
18 are you asking for a specific number of
19 hours?

20 Q. Yes, please.

21 A. I would have to estimate. I
22 don't know off the top of my head. But I
23 would estimate that at this point I
24 probably have spent 50 to 60 hours.

1 Maybe more. 70.

2 Q. So somewhere between 50 and
3 70 hours?

4 A. That is my estimate. But I
5 can -- if a more accurate estimate is
6 required, I can go to my records.

7 Q. Okay. And how much time did
8 you spend writing your report?

9 A. It's a long -- it's a long
10 report. I spent probably -- probably
11 about 50 of those hours writing -- 40 to
12 50 hours spent writing the report.

13 Q. Did anyone else besides
14 counsel assist you in preparation of your
15 report?

16 MS. RELKIN: Objection to
17 form.

18 THE WITNESS: I have a
19 research assistant, Caroline
20 Rutherford, who helped with the
21 references, managing the reference
22 software. She also generated the
23 figures using the publicly
24 available CDC WONDER data on the

1 rates of drug overdose in the --
2 in Summit and Cuyahoga County and
3 nationally. And so she assisted
4 again with administrative matters
5 in figure generation.

6 There was also a doctoral
7 student at Columbia University who
8 was working with me who very early
9 on sent me some literature. But
10 it was largely literature I
11 already had, and he then got busy
12 with his dissertation and didn't
13 do any more work with it.

14 But I wrote the report on my
15 own.

16 BY MR. HERMAN:

17 Q. And after -- did you say
18 your student was named -- I'm sorry, was
19 it Caroline?

20 A. Caroline is -- she is also
21 my student. She -- but she's also my
22 full-time employee. She's a master --
23 she is getting her master's in data
24 science at Columbia University. Her name

1 is Caroline Rutherford.

2 Q. And after Ms. Rutherford
3 generated those figures for you, did you
4 check her work?

5 A. Yes.

6 Q. Okay. And you said that you
7 wrote your report. Did anyone provide
8 you with an outline for your report?

9 A. No.

10 Q. Are you the original drafter
11 of everything in your report?

12 A. Yes.

13 MS. RELKIN: I'm going to
14 object. You're going beyond, I
15 mean, Rule 26. But it's fine.

16 BY MR. HERMAN:

17 Q. Are you the original drafter
18 of everything in your report?

19 A. Yes.

20 Q. Did anyone provide you with
21 language to include in your report?

22 A. No.

23 Q. Did you personally review
24 every study cited in your report?

1 A. Yes.

2 Q. Did you personally review
3 everything listed as materials that you
4 considered?

5 A. I'm sorry. Say the question
6 again.

7 Q. Did you personally review
8 everything listed as materials that you
9 considered both on -- in your report and
10 in the supplemental list?

11 A. Yes.

12 Q. Did you carefully review
13 your report before submitting it?

14 A. Yes, I did.

15 Q. Besides preparation for this
16 deposition and preparing your report,
17 have you spent time on any other matters
18 connected to this case?

19 MS. RELKIN: Objection to
20 form. Objection.

21 THE WITNESS: Say the
22 question again.

23 BY MR. HERMAN:

24 Q. Besides preparing for the

1 deposition, I think we talked about three
2 meetings that were --

3 A. Yeah.

4 Q. -- two to three hours each.

5 I think the last one you said was four
6 hours actually. And preparing your
7 report which you spent -- said you spent
8 40 to 50 hours on, have you spent time on
9 anything else?

10 A. No.

11 MS. RELKIN: And note my
12 objection.

13 BY MR. HERMAN:

14 Q. I'm going to hand you what
15 we've previously marked as Exhibit 1
16 which is your expert report.

17 (Document marked for
18 identification as Exhibit
19 Keyes-1.)

20 BY MR. HERMAN:

21 Q. And I'm also going to hand
22 you a binder, I thought it might be more
23 manageable to flip the binder.

24 A. Thank you.

1 Oh, so this is the same
2 thing.

3 Q. Yes, I just thought rather
4 than flipping something with the clip, it
5 might be easier with the binder.

6 A. Okay.

7 Q. Professor Keyes, I just want
8 to quickly just go through your report at
9 a high level. If you could turn to
10 Page 2. And Roman numeral II is -- has a
11 heading "Opinions," correct?

12 A. Yes.

13 Q. And on Page 2 to 3 under
14 that heading "Opinions," there are 11
15 bullet points. And the 11 bullet
16 points -- I'm sorry, are there 11 bullet
17 points?

18 A. I'm sorry, I have to count
19 them again.

20 MS. RELKIN: Do you want her
21 to count?

22 THE WITNESS: 11.

23 BY MR. HERMAN:

24 Q. Okay. And those bullet

1 points contain the opinions that you
2 intend to offer in this case?

3 A. Yes.

4 Q. Do you intend to offer any
5 opinions besides those listed in the 11
6 bullet points?

7 A. No.

8 MS. RELKIN: Just,
9 objection. Obviously her entire
10 report.

11 THE WITNESS: Yeah, I mean
12 the rest of -- the report contains
13 all my opinions. This is a
14 summary of them. If there are
15 other opinions in the report, they
16 are my opinions.

17 These are -- this is a
18 summary of what is in the report.
19 But should there be other opinions
20 in the report, they are my
21 opinions.

22 BY MR. HERMAN:

23 Q. But the report contains the
24 sum total of your opinions?

1 A. Yes.

2 Q. Do you intend to -- okay.

3 In -- in reaching the
4 opinions in this case, were you asked to
5 make any assumptions?

6 A. Can you give me an example.

7 Q. Well, did your lawyers ask
8 you to assume any facts?

9 MS. RELKIN: Objection to
10 form.

11 MR. SHKOLNIK: Objection.

12 MS. RELKIN: Counsel, you've
13 already been instructed about the
14 "your lawyers."

15 You can say lawyers for the
16 plaintiffs.

17 MR. HERMAN: Sorry. Sorry.

18 BY MR. HERMAN:

19 Q. The lawyers -- did the
20 lawyers for the plaintiffs ask you to
21 make any assumptions in forming your
22 opinions?

23 A. Not to my knowledge.

24 Q. Did you make any assumptions

1 in forming your opinions?

2 MS. RELKIN: Objection to
3 form.

4 THE WITNESS: I don't know
5 what you mean by assumptions.

6 BY MR. HERMAN:

7 Q. Did you assume any facts?

8 A. Could you give me an
9 example? I don't -- I don't know what
10 that means.

11 Q. Okay. Well, did you rely
12 on -- all -- are all your opinions based
13 on the literature and material that you
14 reviewed?

15 A. My opinions are based on the
16 epidemiological literature that I
17 reviewed.

18 Q. Okay. And not something
19 that was provided to you outside those
20 materials?

21 A. Anything that is referenced
22 in the report are materials that I
23 draw -- drew upon to form my opinions.

24 Q. Okay. And -- and nothing

1 else? You didn't rely on other materials
2 or other facts outside of those studies
3 to form your opinions?

4 A. I -- I have a Ph.D. in
5 epidemiology. I relied on my expertise
6 more broadly. But the actual opinions
7 are based on the scientific literature.
8 But I come to it with a large set of
9 skills formed with my degrees.

10 Q. Okay. Did you rely on the
11 opinions of any other plaintiffs' experts
12 in forming your opinions?

13 A. No.

14 Q. If you could turn to
15 Page 41. And Pages 41 to 50 contain a
16 list of the references cited in your
17 report; is that correct?

18 A. Yes.

19 Q. Okay. And those are the
20 materials that support your opinions?

21 A. These are the materials that
22 I cited in the report, yes.

23 Q. And that you relied on for
24 your opinions?

1 A. Yes.

2 Q. Are you relying on materials
3 that are not cited in the body of your
4 report listed on Pages 41 to 50 to
5 support your opinions?

6 A. Again, I mean, I think --

7 MS. RELKIN: Objection.

8 THE WITNESS: -- that I --
9 the opinions that I draw on, when
10 they are based in scientific
11 literature, that scientific
12 literature is cited.

13 I also bring an ability to
14 evaluate scientific literature
15 through my expertise in
16 epidemiology. So not every -- you
17 know, I've written two textbooks
18 on epidemiological methods. I
19 know this literature and other
20 literature and epidemiological
21 methods very well. And so the
22 facts that I draw on for the
23 opinions in this report are based
24 on the scientific literature that

1 I cite. But I come to the table
2 with a broad range of
3 methodological skills to evaluate
4 scientific literature.

5 BY MR. HERMAN:

6 Q. Okay. I -- I understand
7 you're bringing some experience and that
8 that's what you're alluding to. And I'm
9 not trying to discount that.

10 What I'm trying to ask you,
11 and I think you've answered it, is that
12 the facts and the opinions you have in
13 your report rely on the materials that
14 you've cited in your report and your
15 experience?

16 A. That's correct.

17 Q. And at Page 50 that's a copy
18 of your CV?

19 A. And I think that starts on
20 Page 51. Well, page 50 is still the
21 references, so the next page starts my
22 CV.

23 Q. I apologize. 51, and that
24 goes for a while. And that's your CV.

1 Is that an up-to-date CV?

2 A. No. That was prepared on
3 December 18, 2018.

4 Q. Okay. So the notation at
5 the bottom, last updated 3/25/2019 is
6 incorrect?

7 A. I'd have to double-check
8 that. I'm not sure. Given those
9 discrepant dates exactly when it was
10 updated.

11 Q. Did you not do the updating?

12 A. I'm sure I did the updating.
13 I'm just not sure why those two dates are
14 discrepant, so I'd have to look at that.

15 Q. Do you have a more recent
16 CV?

17 A. I -- I have -- I can send a
18 more recent CV if that -- I mean, it
19 would just be a longer list of
20 publications probably.

21 Q. Well, I will -- I'd ask that
22 you provide us with a more up-to-date CV.

23 A. Absolutely.

24 Q. And then after your CV is a

1 list of publications from 2009 to 2019?

2 A. Yes.

3 Q. And based on your answer in
4 my last question, I assume that is no
5 longer an up-to-date list?

6 A. There might be several more
7 publications since the time this was
8 submitted. It was several months ago.
9 And I'm prolific.

10 Q. As you said you'll provide
11 that.

12 A. Sure.

13 Q. Okay. And then if we turn a
14 few pages further. There is a chart
15 that's called "Keyes Considered"?

16 A. Yes.

17 Q. Okay. And that's the list
18 of materials that you considered that was
19 provided with your report?

20 A. Yes.

21 Q. Okay. And what role, if
22 any, did the materials considered play in
23 formulating your opinions?

24 A. They were papers that I --

1 papers or other sources that I read
2 and -- and I evaluated them for whether
3 they formed the basis for my opinions.

4 Q. Okay. And the ones that you
5 decided that form the basis are the ones
6 that you cited as references?

7 A. Say that again.

8 MS. RELKIN: Objection to
9 form.

10 BY MR. HERMAN:

11 Q. Not every material on your
12 list of materials considered is cited as
13 a reference in your report?

14 A. Right.

15 Q. So my question is, you said
16 you reviewed all the materials
17 considered, and then you selected from
18 those the ones that supported your
19 opinion.

20 A. I wouldn't -- I wouldn't
21 phrase it in that way. I would say that
22 I reviewed a body of evidence and the
23 evidence that was germane to the topic at
24 hand is what is cited.

1 Q. Okay. And that's -- the
2 cited materials is what you relied on for
3 your opinions?

4 MS. RELKIN: Objection.

5 THE WITNESS: The cited --
6 can you rephrase that.

7 BY MR. HERMAN:

8 Q. The materials cited in your
9 report are the ones that you relied on
10 for your opinions?

11 A. Yes.

12 Q. And in the materials
13 considered, there's a list of five
14 depositions. It's, I believe, on the
15 second-to-last page. How did you figure
16 out which depositions to look at?

17 MS. RELKIN: Objection to
18 form.

19 THE WITNESS: These were
20 provided to me.

21 BY MR. HERMAN:

22 Q. Did you ask for all the
23 depositions in the case?

24 MS. RELKIN: Objection.

1 THE WITNESS: I have not.

2 No, I have -- I'm sure there's
3 many, many depositions. I have
4 not asked for all the depositions.

5 BY MR. HERMAN:

6 Q. These are ones that were
7 selected to you by plaintiffs' counsel?

8 A. These were materials that
9 were provided to me because they were
10 germane to the -- to the topic.

11 Q. They were provided to you by
12 plaintiff's counsel?

13 A. Yes.

14 Q. And did you have any input
15 into what depositions the plaintiff's
16 counsel decided to provide you?

17 MS. RELKIN: Objection to
18 form.

19 THE WITNESS: There was no
20 discussion of the broader range of
21 the universe of depositions. So
22 these were particular depositions
23 that they thought would be useful
24 in allowing me to understand what

1 was going on at the county level.

2 BY MR. HERMAN:

3 Q. Did you read each of these
4 five depositions in its entirety?

5 A. I reviewed them. You know,
6 to say I read them, you know, I reviewed
7 them to the extent that they were useful
8 in formulating an understanding of what
9 was going on in the counties.

10 Q. Did you -- did you read them
11 in their entirety?

12 MS. RELKIN: Objection to
13 form.

14 THE WITNESS: For the
15 most -- I read them. I don't --
16 yeah. The majority of them I
17 looked at, I saw whether they were
18 useful in formulating my
19 understanding of what was
20 happening in the counties. Some
21 were more useful than others. I
22 wouldn't say that I read every
23 single one cover to cover in its
24 entirety because some I think were

1 more useful than others.

2 BY MR. HERMAN:

3 Q. Did anyone point you to
4 specific portions of the depositions?

5 A. No.

6 Q. Okay. And then you've got,
7 on the next page, a list of 20 documents
8 produced in the litigation.

9 A. Mm-hmm.

10 Q. Do you know how many
11 documents have been produced in the
12 litigation?

13 A. No.

14 Q. How did you figure out what
15 documents to look at?

16 MS. RELKIN: Objection to
17 form.

18 THE WITNESS: These were the
19 list of documents that were made
20 available to me.

21 BY MR. HERMAN:

22 Q. And when you say made
23 available to you, do you mean provided to
24 you by plaintiffs' counsel?

1 A. Yes.

2 Q. Are you aware that none of
3 the documents on this list were
4 provided -- were produced by defendants
5 in this case?

6 A. Am I -- sorry say that
7 again.

8 Q. Are you aware none of the
9 documents on this list were produced by
10 defendants in this case?

11 A. I was not privy to the
12 source, the -- which documents were
13 produced by whom.

14 Q. Did you conduct any
15 interviews before preparing your report?

16 A. Interviews?

17 Q. Interviews of, for example,
18 individuals who work for Cuyahoga County?

19 A. No.

20 Q. Did you -- you didn't
21 conduct any interviews?

22 A. I did not conduct
23 interviews.

24 Q. Okay. Did you ask to?

1 A. You know, I'm an
2 epidemiologist. I study population
3 aggregate data. I don't -- that's not
4 within the scope of what this report
5 entails.

6 Q. So the answer is that you
7 didn't ask to speak to anyone?

8 A. The answer is that, as an
9 epidemiologist, you know, I don't do
10 interviews with individuals. I study
11 population level trends.

12 MR. HERMAN: Can I have the
13 supplemental list.

14 (Document marked for
15 identification as Exhibit
16 Keyes-2.)

17 BY MR. HERMAN:

18 Q. I'm handing you what's been
19 marked as Exhibit 2, which is a
20 supplemental list of materials that was
21 provided to us by plaintiffs' counsel. I
22 believe on April 23rd, 2019.

23 And, Professor Keyes, a few
24 times you've referenced additional

1 materials that you reviewed after
2 preparing your report. Is this a
3 complete list of the materials?

4 A. To my knowledge, yes.

5 Q. And I think you said that
6 the transcripts that were reviewed on --
7 that are listed here were provided to you
8 by plaintiffs' counsel?

9 A. I'm sorry. Say that -- the
10 transcripts that were --

11 Q. The five deposition
12 transcripts that are listed on the
13 supplemental materials considered list.

14 A. The four? I think it's
15 four.

16 Q. I apologize. Four. The
17 four deposition transcripts were provided
18 to you by plaintiffs' counsel?

19 A. Yes.

20 Q. When did you prepare your
21 report?

22 A. I began preparing it around
23 January of 2019. And worked on it
24 through around March when it was

1 submitted.

2 Q. Is there any reason that you
3 didn't review these depositions before
4 submitting your report?

5 A. Is there -- what do you mean
6 by reason?

7 Q. Well, they're all -- they're
8 all dated prior to the submission of your
9 report, correct?

10 A. Yes.

11 Q. And so they were available
12 to you at the time that you submitted
13 your report?

14 MS. RELKIN: Objection to
15 form.

16 THE WITNESS: Yes. You
17 know, my report is on the
18 epidemiological evidence. I
19 mostly relied on the peer-reviewed
20 literature and the grey literature
21 that I cite in the report. I
22 didn't rely on transcripts.

23 BY MR. HERMAN:

24 Q. And then there are two New

1 England Journal medical -- of Medicine
2 articles?

3 A. Mm-hmm.

4 Q. And how did you locate those
5 articles?

6 A. I'm an avid reader of the
7 scientific literature. And so as a
8 scientist, I regularly read the journals.

9 Q. And so you just found them
10 after you submitted your report while you
11 were reading The New England Journal of
12 Medicine?

13 MS. RELKIN: Objection.

14 THE WITNESS: I regularly
15 read The New England Journal of
16 Medicine. I think these came up
17 in my -- in my -- the regular
18 course of my scientific practice.

19 BY MR. HERMAN:

20 Q. Okay. What role, if any,
21 did the materials listed on your
22 supplemental list play in formulating
23 your opinions in this case?

24 A. These materials didn't

1 change any of the opinions in the -- in
2 the statement.

3 Q. Going back to your report.
4 On Pages 4 to 10 of your report, those
5 are all under the heading at Roman
6 numeral Number III, "Methodology"?

7 A. Mm-hmm, yes.

8 Q. And this is a section of the
9 report where you lay out your methodology
10 that you used to form your opinions?

11 A. Yes.

12 Q. Does this section describe
13 how you assembled and reviewed the
14 materials discussed in your report?

15 A. That begins on Page 8.

16 Q. Under the heading A.3?

17 A. Yes.

18 Q. And A.3.1 is the literature
19 review search strategy?

20 A. Yes.

21 Q. And did you conduct a --
22 excuse me. Did you conduct a systematic
23 review to reach your opinions in this
24 case?

1 A. I conducted a critical
2 review, including searching the
3 literature for topics that were germane
4 to the opinions that I was -- the -- the
5 topics that I was asked to review.

6 Q. And what -- what is the
7 difference between a critical review and
8 a systematic review?

9 MS. RELKIN: Objection to
10 form.

11 THE WITNESS: I don't --
12 what I did in -- as a search
13 strategy is that I reviewed the
14 literature, including searching
15 PubMed as I've described here.
16 And then from that literature
17 search found additional articles
18 using standard practices that are
19 used in literature reviews that
20 are published in the peer-reviewed
21 literature. I didn't do anything
22 different than I do in -- in
23 peer-reviewed literature.

24 BY MR. HERMAN:

1 Q. Okay. In your academic
2 work, how long does it take you to do a
3 literature review that you're submitting
4 for publication?

5 MS. RELKIN: Objection to
6 form. Overbroad.

7 THE WITNESS: It depends on
8 the topic.

9 BY MR. HERMAN:

10 Q. Okay. How long would it
11 typically take you to do a literature
12 review on -- that you were going to
13 submit to -- for publication on the
14 topics that you covered in your report?

15 MS. RELKIN: Objection to
16 form.

17 THE WITNESS: It would
18 depend on the scope of the paper.
19 I couldn't -- I couldn't provide
20 one single answer to that
21 question.

22 BY MR. HERMAN:

23 Q. Okay. Well, on average, how
24 long does it take you to do a literature

1 review in your academic work?

2 MS. RELKIN: Objection.

3 THE WITNESS: Again, it
4 really depends on the topic, the
5 scope, the collaborators. It's
6 not -- I don't think that there's
7 a single average time that I could
8 cite.

9 BY MR. HERMAN:

10 Q. Are you aware that there are
11 studies on how long it takes typically to
12 do a literature review?

13 MS. RELKIN: Objection.

14 THE WITNESS: I would have
15 to review those studies for their
16 rigor.

17 BY MR. HERMAN:

18 Q. When conducting a literature
19 review, is it standard practice to
20 disclose the criteria for inclusion and
21 exclusion of studies?

22 MS. RELKIN: Objection.

23 Overbroad.

24 THE WITNESS: It depends on

1 the nature and scope of the
2 literature review.

3 BY MR. HERMAN:

4 Q. When you're typically
5 writing -- in your academic work, would
6 you submit a paper that relied on
7 literature review without a description
8 of the inclusion and exclusion criteria?

9 A. Again, it depends on what
10 type of literature review you're
11 conducting. If it's a critical narrative
12 review, sometimes that's included.
13 Sometimes it's not. It's standard
14 practice in the peer-reviewed literature
15 to use the methodology that I used in
16 reviewing this literature.

17 Q. You would agree with me that
18 most of the studies that you reference in
19 your report include inclusion/exclusion
20 criteria when they're doing a literature
21 review?

22 MS. RELKIN: Objection.

23 Overbroad.

24 THE WITNESS: I would have

1 to go through each one of the
2 articles that I cited. So I
3 couldn't agree or disagree without
4 reviewing them.

5 BY MR. HERMAN:

6 Q. You don't agree that it's
7 standard practice to include inclusion
8 and exclusion criteria in a literature
9 review?

10 MS. RELKIN: Objection to
11 form. Overbroad.

12 THE WITNESS: It depends on
13 what type of literature review
14 that is conducted. So no, I
15 wouldn't agree with that.

16 BY MR. HERMAN:

17 Q. Okay. Well, what type of
18 literature review would you include
19 inclusion/exclusion criteria?

20 A. A literature review that --
21 that included them.

22 Q. Well, you said it depends on
23 the type. So what type would you include
24 it for?

1 A. You know, I -- I don't think
2 that I would be comfortable saying
3 there's one specific type of literature
4 review. If you look in the scientific
5 literature, there's all kinds of
6 different ways of doing literature
7 searches and literature reviews. Some
8 have specific inclusion/exclusion
9 criteria. Others are more critical
10 reviews based on the topic.

11 Q. Does your list of materials
12 consider -- list every article that you
13 located in your searches?

14 MS. RELKIN: Objection to
15 form.

16 THE WITNESS: I'm sorry.
17 Say that question again.

18 BY MR. HERMAN:

19 Q. Did your list of materials
20 considered include every article that you
21 located in your searches?

22 MS. RELKIN: Objection to
23 form.

24 THE WITNESS: You know, I --

1 I have 15 years of expertise in
2 studying opioid use disorders and
3 I'm -- over the years, you know, I
4 have developed that expertise
5 through my epidemiological work.

6 So I cite in here all of the
7 articles that I reviewed to form
8 the opinions. But those were --
9 you know, my expertise in opioid
10 use disorders, including my
11 expertise in these literatures was
12 formed over 15 years.

13 BY MR. HERMAN:

14 Q. I understand what is cited
15 in your report, but does your list of
16 materials considered include a list of
17 every article that you located in the
18 searches you ran?

19 A. Again, I -- to answer that
20 question, I can -- I -- I point to the --
21 the material that I cited in the report
22 as the material that is germane to the
23 topic. It was developed over a long
24 period of time of developing the

1 expertise in the topic.

2 Q. Materials that you decided
3 were germane to the topics?

4 MS. RELKIN: Objection to
5 form.

6 THE WITNESS: Materials that
7 as an expert in this area, I have
8 the expertise to locate as germane
9 to the topic.

10 BY MR. HERMAN:

11 Q. Okay. But they are
12 materials that you personally decided
13 were germane to the topic?

14 A. I think that in my -- in my
15 statement I have the levels of evidence
16 that I considered.

17 So I think that that is
18 outlined in Section A.3.2.

19 Q. Yeah. Professor Keyes, I'm
20 going to ask you to just try to
21 concentrate on the question that I'm
22 asking.

23 So my first question is:
24 Does the list of materials considered

1 include every article that you located in
2 your searches?

3 MS. RELKIN: Objection to
4 form. Asked and answered.

5 THE WITNESS: I believe I've
6 answered the question.

7 BY MR. HERMAN:

8 Q. I don't believe you have.
9 So it may be my mistake, but I'm going to
10 ask you to do it again.

11 Does the list of materials
12 considered include every article that you
13 located in your searches?

14 MS. RELKIN: Objection to
15 form.

16 THE WITNESS: So again, what
17 I have cited in this report are
18 the articles that are specifically
19 germane to the topics. They were
20 formed over a long period of time
21 given my expertise.

22 Anything that I considered
23 to form the opinions that I did
24 not cite in the report are in the

1 materials considered.

2 BY MR. HERMAN:

3 Q. Okay.

4 A. I'm a -- you know, I read
5 the scientific journals. I'm the editor
6 of three journals. I --

7 Q. Yes.

8 A. There's thousands of
9 articles on opioid use disorders.

10 Q. I understand that. But you
11 decided what you believed was germane,
12 and that's what you referenced, correct?

13 A. I used --

14 MS. RELKIN: Just objection
15 to form. Argumentative.

16 THE WITNESS: -- my
17 expertise to cite the literature
18 that forms the opinions.

19 BY MR. HERMAN:

20 Q. Okay. But if I wanted to go
21 back and evaluate what you decided was
22 not germane, would I have the ability to
23 do that?

24 A. I don't understand the

1 question.

2 Q. Well, the reason I'm
3 asking -- and I'm going to ask it again.
4 Does the list of materials considered
5 include every article that you located in
6 your searches?

7 MS. RELKIN: Objection to
8 form.

9 THE WITNESS: I believe that
10 I've answered the question.

11 BY MR. HERMAN:

12 Q. Is the answer to my question
13 yes or no?

14 A. So as I've stated --

15 Q. No, no, no. Hold on. I
16 don't mean to interrupt you --

17 MS. RELKIN: You just
18 interrupted her.

19 MR. CIACCIO: You can't stop
20 the witness.

21 MR. HERMAN: She's not
22 answering the question.

23 MR. CIACCIO: I don't care.
24 Let her answer the question.

1 MS. WINNER: Counsel, I
2 think there needs to be -- I
3 shouldn't be speaking, but you
4 shouldn't be speaking either. I
5 think we need to have one lawyer
6 defending this witness.

7 MR. SHKOLNIK: Cuyahoga
8 County is allowed to -- Cuyahoga
9 County is allowed to speak at
10 these depositions.

11 MS. RELKIN: You did
12 interrupt her.

13 MS. WINNER: We have three
14 so far.

15 MR. SHKOLNIK: I'll stop --
16 let Joe do the talking for
17 Cuyahoga County.

18 BY MR. HERMAN:

19 Q. You have a list of materials
20 considered, right?

21 A. Yes.

22 Q. Is every article that you
23 located in your searches on that list?

24 MS. RELKIN: Objection to

1 form as to "located in your
2 searches."

3 THE WITNESS: Again, I -- I
4 have outlined in this report what
5 my search strategy was in order to
6 form these opinions. The
7 materials that I reviewed that I
8 felt were informative to forming
9 my opinions are cited in the
10 report. Everything else is in the
11 materials considered.

12 BY MR. HERMAN:

13 Q. Okay. So every article that
14 you reviewed is listed in the materials
15 considered?

16 A. You know, again, I -- I
17 have -- I think what I've outlined here
18 is my approach to doing this review,
19 which is consistent with how I have done
20 peer-reviewed literature searches in the
21 published literature.

22 Q. But isn't the reason for
23 listing -- including a list of materials
24 that you've included or excluded, so

1 someone who is going back and looking at
2 the work that you did can evaluate what
3 criteria you applied to include or
4 exclude material?

5 MS. RELKIN: Objection to
6 form.

7 THE WITNESS: There are some
8 literature reviews that use that
9 strategy. There are others that
10 are in the medical literature that
11 don't use that strategy. And
12 those include critical reviews by
13 experts.

14 BY MR. HERMAN:

15 Q. Would I, as a non-expert, be
16 able to go back and look at the list that
17 you provided and determine what you
18 decided was not germane to your opinions?

19 MS. RELKIN: Objection to
20 form.

21 THE WITNESS: I can't answer
22 that question for you.

23 BY MR. HERMAN:

24 Q. Well, is there a list

1 somewhere that -- does the list of
2 materials include everything that you
3 reviewed to decide whether something was
4 germane or not germane?

5 A. So what I -- if -- if you
6 read my Section A.3, I think it clearly
7 lays out the methodology that I used as
8 an expert in this topic to form the
9 opinions that I formed. And that
10 included citing literature that was
11 relevant to the topics that I discussed.

12 Q. And did you keep a record of
13 the searches that you ran?

14 A. Again, I would point you to
15 Section A.3 where I review the
16 methodology that I used for the evidence.
17 I was asked to review a wide range of
18 topics. So there's not one set of search
19 terms that's going to be applicable to
20 both medication-assisted treatment and
21 heroin use after prescription opioid use.

22 Q. Did you keep a record of the
23 search terms that you used?

24 MS. RELKIN: Objection.

1 Asked and answered.

2 THE WITNESS: In Section
3 A.3, I review the methodology that
4 I used. It included doing
5 searches on PubMed, but then also
6 a much more expansive review of
7 the literature based on my
8 expertise using papers that are
9 germane to the topics.

10 BY MR. HERMAN:

11 Q. Would the methodology that
12 you lay out in Section A.3, allow someone
13 to replicate what you did?

14 MS. RELKIN: Objection to
15 form. Asked and answered.

16 THE WITNESS: Yeah, I feel
17 like I've answered the question.
18 This is a -- this is a critical
19 review of the literature based on
20 my expertise.

21 BY MR. HERMAN:

22 Q. That wasn't my question. My
23 question was, does the methodology you
24 lay out in Section A.3 allow someone to

1 replicate what you did?

2 MS. RELKIN: Objection.

3 THE WITNESS: If they had
4 the same level of expertise, I
5 would assume that the same person
6 in reviewing the medical
7 literature would develop the same
8 conclusions if that's the
9 question.

10 BY MR. HERMAN:

11 Q. Wouldn't they need to know
12 the search terms you used?

13 A. Again, what I have done --

14 MS. RELKIN: Objection.
15 Argumentive.

16 THE WITNESS: -- in this
17 report is a critical review of the
18 literature based on my expertise.

19 BY MR. HERMAN:

20 Q. To repeat what you did, your
21 methodology, wouldn't someone need to
22 know the search terms?

23 MS. RELKIN: Objection.

24 Asked and answered. Argumentive.

1 THE WITNESS: I -- so what
2 I've done and laid out in Section
3 A.3 is that what I performed was a
4 critical review of the literature
5 based on my expertise. That
6 included searching the topics on
7 PubMed and including a wide
8 variety of other literatures that
9 I then identified.

10 BY MR. HERMAN:

11 Q. Professor Keyes, I feel like
12 we're missing each other here. Because
13 my question is, without the search terms
14 would someone applying the methodology
15 that you used in A.3 be able to replicate
16 what you did?

17 MS. RELKIN: Objection.
18 Counsel, this is like the tenth
19 time that you've asked the
20 question.

21 MR. HERMAN: First off --

22 MS. RELKIN: She's answered
23 it.

24 MR. HERMAN: She has not

1 answered it.

2 MS. RELKIN: She's answered
3 it.

4 MR. HERMAN: If she keeps
5 being evasive, we're going to need
6 a second day. So, I mean, I'm
7 asking the question. I'd like an
8 answer to my question.

9 MS. RELKIN: If you want to
10 waste your time asking the same
11 question ten times because you
12 don't like the answer, that's your
13 choice.

14 MS. DO AMARAL: There won't
15 be a second day.

16 THE WITNESS: So in Section
17 A.3.1 I outline my literature
18 search strategy. I cannot speak
19 to what someone else who was
20 undergoing the same tasks that I
21 was asked to do -- I don't -- it's
22 a hypothetical question that I
23 don't -- I've outlined my strategy
24 here.

1 BY MR. HERMAN:

2 Q. Okay. But they wouldn't
3 know what you decided was germane or not
4 germane?

5 MS. RELKIN: Objection.

6 BY MR. HERMAN:

7 Q. Right?

8 A. So I have outlined here how
9 I decided what was germane and not
10 germane based on my expertise.

11 Q. Okay. You ran PubMed --
12 searches in PubMed, right?

13 A. Yes.

14 Q. Are there other databases
15 commonly used in literature reviews?

16 MS. RELKIN: Objection.

17 THE WITNESS: There are
18 other search engines that are
19 available.

20 BY MR. HERMAN:

21 Q. EMBASE?

22 A. Again, there are other
23 search engines that are available.

24 Q. Is EMBASE one of those

1 search engines?

2 A. I do not use -- I don't
3 regularly use EMBASE.

4 Q. Cochrane?

5 A. Cochrane is a search engine.

6 Q. Okay. Why did you limit
7 your search to PubMeds?

8 A. I think PubMed is a
9 comprehensive resource for peer-reviewed
10 literature. It's commonly used in my
11 field. Most peer-reviewed publications
12 of the 250 or so that I've published have
13 been based on literature searches in
14 PubMed.

15 Q. Did you locate -- did you
16 locate all the articles that you relied
17 on in your expert report personally?

18 A. Did I locate personally all
19 of the articles?

20 MS. RELKIN: Objection.

21 THE WITNESS: I reviewed
22 every single article that is cited
23 in this report. And it was based
24 on literature searches that I did.

1 As I mentioned, I have a
2 research assistant, Caroline
3 Rutherford, who helped me gather
4 references. I also had a doctoral
5 student, David Fink, who provided
6 me with some references early on.
7 But I personally reviewed every
8 paper that was cited.

9 BY MR. HERMAN:

10 Q. Were any of the papers cited
11 provided by counsel?

12 A. I -- my literature -- my
13 literature search was very comprehensive,
14 and so there was discussion of papers,
15 but there was no influence of counsel.

16 Q. Did any --

17 MS. RELKIN: I'm just going
18 to counsel you not to discuss what
19 you spoke to counsel about.

20 BY MR. HERMAN:

21 Q. Yeah, I'm not asking you for
22 the substance of conversation. But did
23 plaintiffs' counsel provide you with
24 articles that you relied on in your

1 expert report?

2 MS. RELKIN: Objection.

3 THE WITNESS: To my
4 knowledge, the literature that I
5 gathered was based on my
6 discussions with other -- my --
7 the two people that I cite on --
8 in the paper, in the report.

9 BY MR. HERMAN:

10 Q. Were they all located from
11 searches in PubMed?

12 A. And then reviewing the
13 articles themselves, and their reference
14 lists and kind of expanding from there.

15 Q. Okay. What's a hypothesis?

16 A. What is a hypothesis?
17 That's a really good question. So a
18 hypothesis is a statement about a
19 prediction about the way in which
20 something operates.

21 Q. Okay. Before deciding a
22 hypothesis is correct, is it important to
23 consider alternative hypotheses?

24 MS. RELKIN: Objection to

1 form. Overbroad. But you can
2 answer it.

3 THE WITNESS: So -- in terms
4 of the scientific method? The
5 more -- the general scientific
6 method? So usually we present a
7 hypothesis and then we test that
8 hypothesis against an alternative.

9 BY MR. HERMAN:

10 Q. Before deciding your
11 hypothesis is correct, you need to rule
12 out alternative hypotheses?

13 MS. RELKIN: Objection to
14 form. Overbroad.

15 THE WITNESS: Yeah, I mean I
16 wouldn't say that that's
17 explicitly the entirety of the
18 scientific method. But hypotheses
19 are tested in science.

20 BY MR. HERMAN:

21 Q. Okay. And before deciding
22 your hypothesis is correct, do you need
23 to rule out alternative hypotheses?

24 MS. RELKIN: Same objection.

1 THE WITNESS: It depends on
2 the hypothesis.

3 BY MR. HERMAN:

4 Q. What do you mean by that?

5 A. I mean, there's -- you know,
6 in -- I think you can -- there's many
7 philosophers of science, including Popper
8 and Kuhn, who evaluate the broad range in
9 which scientific hypotheses are developed
10 and evaluated. And certainly alternative
11 hypotheses and evaluating them are part
12 of the scientific process.

13 Q. In your academic work before
14 you decide a hypothesis is correct, do
15 you rule out alternative hypotheses?

16 A. There's a broad range of
17 hypotheses that are tested in science,
18 and of course considering alternative
19 hypothesis is always an important part of
20 that method.

21 Q. Professor Keyes, in your
22 report you define prescription opioids as
23 medications indicated for the control of
24 moderate and severe -- severe pain,

1 correct?

2 A. On Page 4 I say,
3 "Prescription opioids are medications
4 indicated for the control of moderate to
5 severe pain and include natural opioid
6 analgesics." And -- and then I define
7 some of them.

8 Q. What does it mean for a
9 medication to be indicated for the
10 control of moderate to severe pain?

11 A. I think what I meant in that
12 section is what prescription opioids are
13 predominately used for in medical
14 practice.

15 Q. They are understood as
16 beneficial for moderate to severe pain?

17 A. I --

18 MS. RELKIN: Objection to
19 form.

20 THE WITNESS: I think that
21 there's controversy around that
22 statement. But I'm saying what
23 they are used for.

24 BY MR. HERMAN:

1 Q. Okay. Have -- have you
2 yourself written articles that say
3 prescription opioids have medical
4 benefits?

5 A. I have written that in
6 articles in the past.

7 Q. You define medical use of
8 prescription opioids to refer to the use
9 of prescription opioids based on a
10 physician prescription and used as
11 directed by physician, correct?

12 MR. CIACCIO: If you're
13 going to cite from the report, can
14 you just give a page number so --

15 MR. HERMAN: I was just
16 asking the question, but --

17 MR. CIACCIO: But if you're
18 going to cite, you should tell the
19 witness what page you are citing
20 from.

21 THE WITNESS: Yes, I say
22 medical use of prescription
23 opioids as -- that I will refer to
24 it in the report as "use of

1 prescription opioids based on a
2 physician prescription and use as
3 directed by a physician."

4 BY MR. HERMAN:

5 Q. You'd agree that the only
6 legal way to get prescription opioids is
7 to go to a licensed prescriber and obtain
8 a prescription, correct?

9 MS. RELKIN: Objection to
10 form.

11 THE WITNESS: Only legal way
12 to get prescription opioids is to
13 go to a licensed prescriber.

14 Yes.

15 BY MR. HERMAN:

16 Q. You would agree that a
17 prescriber is only supposed to write
18 prescriptions for legitimate medical
19 reasons, correct?

20 MS. RELKIN: Objection.

21 THE WITNESS: I think that
22 prescribers are prescribing based
23 on a set of information that they
24 are given. And that oftentimes

1 that the risks of opioids were
2 overstated. The risk of
3 prescription opioids were
4 overstated.

5 And so I think that
6 physicians are in a difficult
7 position when they are trying to
8 write prescriptions for legitimate
9 medical reasons.

10 MR. HERMAN: Counsel, I'm
11 not sure it's appropriate for you
12 to point to the screen and guide
13 the witness.

14 MS. RELKIN: I think it's
15 clear that she misstated when she
16 said the risks of opioids, that --
17 that that was a misstatement.

18 MR. HERMAN: Well, that's
19 fine. I mean, you can correct
20 that later if you feel a need to.

21 BY MR. HERMAN:

22 Q. My question again is, you'd
23 agree that a prescriber is only supposed
24 to write a prescription for legitimate

1 medical reasons?

2 MS. RELKIN: Objection to
3 form.

4 THE WITNESS: I would have
5 to know what you mean by
6 legitimate medical reasons.

7 BY MR. HERMAN:

8 Q. Well, is a prescriber
9 supposed to write a prescription for
10 reasons other than legitimate medical
11 reasons?

12 MS. RELKIN: Objection.

13 THE WITNESS: I would say in
14 general I think that there has
15 been misinformation to physicians
16 about what the legitimate medical
17 reasons are. And so I can't
18 say -- I can't make a blanket
19 statement about what physicians
20 should and should not be
21 prescribing based on that.

22 BY MR. HERMAN:

23 Q. Is it your belief that
24 prescribers were writing prescriptions

1 for reasons they understood to be
2 illegitimate medical reasons?

3 MS. RELKIN: Objection.
4 Overbroad.

5 THE WITNESS: That's not
6 what I said.

7 BY MR. HERMAN:

8 Q. Well, are prescribers only
9 supposed to write prescriptions for
10 legitimate medical reasons?

11 A. You know, again, I think
12 that that statement relies on the
13 information that the physician has about
14 the risks and benefits.

15 Q. I'm asking you a different
16 question. I'm asking you, are
17 prescribers supposed to write
18 prescriptions for legitimate medical
19 reasons?

20 MS. RELKIN: Objection.

21 THE WITNESS: Are you making
22 a blanket statement of all
23 prescribers, of all prescriptions,
24 and all physicians?

1 BY MR. HERMAN:

2 Q. I'm asking you a question
3 about what prescribers are supposed to
4 do.

5 Are prescribers supposed to
6 write prescriptions for legitimate
7 medical reasons?

8 MS. RELKIN: Objection.
9 Overbroad.

10 THE WITNESS: You know, I
11 think prescribers make decisions
12 based on the information that they
13 have available to them.

14 BY MR. HERMAN:

15 Q. And it's their belief based
16 on the information that they have
17 available to them that they're writing
18 prescriptions for legitimate medical
19 reasons?

20 MS. RELKIN: Objection.
21 Overbroad.

22 THE WITNESS: I wouldn't --
23 I wouldn't speak to every single
24 physician for every single

1 prescription.

2 BY MR. HERMAN:

3 Q. Are you offering an opinion
4 that doctors should not be able to
5 prescribe prescription opioids?

6 A. I'm sorry. I don't
7 understand the question.

8 Am I offering an opinion
9 that doctors should not be able to
10 prescribe prescription opioids? Can you
11 point in the report where I've indicated
12 that?

13 Q. I'm just -- I'm asking you
14 the question. It's not -- it's just a
15 question. Are you offering an opinion
16 that doctors should not be able to
17 prescribe prescription opioids?

18 A. That is not stated in my
19 report.

20 Q. Not everything has to be
21 stated in your report. I'm asking you --

22 A. I'm relying on my report
23 though.

24 Q. Are you offering an opinion

1 in your -- are you offering an opinion
2 that doctors should not be able to
3 prescribe prescription opioids?

4 A. That opinion, I would ask
5 where in the report that I've stated
6 that.

7 Q. So is the answer to my
8 question no?

9 MS. RELKIN: It's a
10 preposterous question.

11 THE WITNESS: I haven't --

12 MS. RELKIN: Badgering the
13 witness.

14 BY MR. HERMAN:

15 Q. You're not offering an
16 opinion that a doctor should not be able
17 to exercise his or her medical judgment
18 in deciding appropriate treatment for a
19 patient?

20 MS. RELKIN: Objection to
21 form. Overbroad.

22 THE WITNESS: What I've
23 stated in the report, and I think
24 the epidemiological evidence is

1 available to support, is that the
2 oversupply of opioids in the
3 United States in the last 15 years
4 is -- part of the reason that
5 occurred is that the risks of
6 prescription opioids were
7 understated. That's what I got
8 wrong earlier. I'm sorry.

9 BY MR. HERMAN:

10 Q. Okay. But again --

11 A. And so --

12 MS. RELKIN: She's still
13 answering.

14 MR. HERMAN: I apologize.

15 THE WITNESS: And so your
16 question is, doctors -- am I
17 offering the opinion that doctors
18 should not be able to exercise
19 their medical judgment?

20 I'm offering the opinion
21 that doctors were not provided
22 with sufficient information with
23 which to make medical judgments in
24 all cases.

1 BY MR. HERMAN:

2 Q. But are you offering an
3 opinion that, today, doctors shouldn't be
4 able to prescribe prescription opioids?

5 MS. RELKIN: Objection to
6 form.

7 THE WITNESS: Again, I've
8 answered that question.

9 BY MR. HERMAN:

10 Q. And what was your answer
11 again?

12 MS. RELKIN: Objection.

13 THE WITNESS: I'm sure it's
14 available in the --

15 BY MR. HERMAN:

16 Q. Humor me and just answer my
17 question, please.

18 A. I'm sorry. Can you restate
19 the question?

20 Q. Are you offering an opinion
21 that doctors should not be able to
22 prescribe prescription opioids?

23 MS. RELKIN: Objection.

24 THE WITNESS: Am I offering

1 an opinion that doctors should not
2 be able to prescribe prescription
3 opioids? I don't -- I don't see
4 where in the report that opinion
5 is stated.

6 BY MR. HERMAN:

7 Q. Are you offering an opinion
8 that any prescription written for a
9 prescription opioid in Cuyahoga County
10 was written for a reason other than a
11 legitimate medical need?

12 MS. RELKIN: Objection.
13 Overbroad.

14 THE WITNESS: I'm sorry.
15 Can you -- are you offering an
16 opinion that any prescription
17 written for a prescription opioid
18 in Cuyahoga County was written for
19 a reason other than a legitimate
20 medical need?

21 I don't -- I would not make
22 blanket statements about all
23 prescriptions written in Cuyahoga
24 County.

1 BY MR. HERMAN:

2 Q. Are you aware of any
3 prescription written in Cuyahoga County
4 that was written for other than a
5 legitimate medical need?

6 MS. RELKIN: Objection to
7 form.

8 THE WITNESS: Again, I would
9 not make blanket statements about
10 all prescriptions written in
11 Cuyahoga County. That's not the
12 basis of my opinion.

13 BY MR. HERMAN:

14 Q. Are you aware of any
15 prescription in Cuyahoga County that was
16 written for a reason other than a
17 legitimate medical need?

18 A. Again, I relied on
19 epidemiological evidence. It's at the
20 population level and applied to the
21 population totals in Cuyahoga County.
22 That's not what the epidemiologic
23 evidence is offered to support or refute.

24 Q. Professor Keyes, are you

1 aware of any prescription that -- for a
2 prescription opioid in Cuyahoga County
3 that was written for a reason other than
4 a legitimate medical need?

5 MS. RELKIN: Objection.

6 Asked and answered. Argumentative.

7 She's answered the question.

8 Let's move on.

9 BY MR. HERMAN:

10 Q. Please answer my question.

11 A. I think I've answered the
12 question that that is not the purpose and
13 scope of what I am doing in an
14 epidemiological analysis of the topics in
15 this report.

16 Q. I understand that is not in
17 your report, but I'm asking you the
18 question. Are you aware, Professor
19 Keyes, of any prescription written in
20 Cuyahoga County for a reason other than a
21 legitimate medical need?

22 MS. RELKIN: Same objection.

23 THE WITNESS: Again, this is
24 not within the scope of the report

1 that I wrote.

2 BY MR. HERMAN:

3 Q. Yeah, but my question is a
4 yes or no question. Are you aware,
5 Professor Keyes, of a prescription for a
6 prescription opioid in Cuyahoga County
7 written for a reason other than a
8 legitimate medical need?

9 MS. RELKIN: Objection.

10 You've asked this at least five
11 times. She's answered it. She is
12 an epidemiologist --

13 MR. HERMAN: She's not --

14 MS. RELKIN: -- she doesn't
15 look at individuals.

16 BY MR. HERMAN:

17 Q. Yes or no. Are you aware?

18 A. The epidemiological evidence
19 that I reviewed is about populations.
20 And I applied it to the specific counties
21 that we are discussing today and I
22 applied it to the broader scientific
23 literature and epidemiology. And that's
24 what I've done in the report.

1 Q. So is the answer that you're
2 not aware of a prescription --

3 A. The answer is that the
4 epidemiology -- what I've been asked to
5 consider is the epidemiology.

6 Q. So are you not -- are you
7 aware of a prescription written in
8 Cuyahoga County for a prescription opioid
9 for a reason other than legitimate
10 medical need?

11 MS. RELKIN: Objection.

12 Asked and answered. Now we are
13 like at eight, the eighth time
14 you've asked that question. Move
15 on. You are badgering.

16 THE WITNESS: My
17 epidemiological analysis is about
18 population level trends, the risk
19 factors and the specific trends of
20 opioid-related harm in the
21 counties and that is what I
22 covered in the report.

23 BY MR. HERMAN:

24 Q. Would you agree that your

1 definition of medical use also highlights
2 that for prescription opioids to be used
3 medically, the patient must use the
4 medications as prescribed?

5 MS. RELKIN: Objection to
6 form.

7 THE WITNESS: My definition
8 that I used in the report for
9 medical use of prescription
10 opioids was medical use will refer
11 to use of prescription opioids
12 based on a physician prescription
13 and use as directed by a
14 physician.

15 BY MR. HERMAN:

16 Q. And so medical use, to use a
17 prescription, medically you have to use
18 it as prescribed by the physician?

19 A. The definition that I use is
20 use as directed by a physician.

21 Q. Do most people who are
22 prescribed opioids develop an opioid use
23 disorder?

24 MS. RELKIN: Objection to

1 form.

2 THE WITNESS: So that is
3 reviewed, the evidence underlying
4 that statement is reviewed in
5 Section B.2 from Page 12 to 16.

6 BY MR. HERMAN:

7 Q. Section B.2 reviews --

8 A. No, I'm sorry. Page 11 to
9 16.

10 So I think the answer to
11 that question is -- is that if you look
12 at the epidemiological evidence regarding
13 the rates of opioid use disorder after
14 medical use of opioids, the available
15 epidemiological evidence indicates that
16 there is generally a dose-response
17 relationship, and that in terms of opioid
18 use disorder from mild to severe, it's
19 about 21 to 29 percent and opioid use
20 disorder for moderate to severe is about
21 8 to 12 percent. And there's a number
22 of --

23 Q. Per -- per --

24 A. -- meta-analyses and reviews

1 and additional papers that came on after
2 those reviews that would support those
3 figures.

4 Q. Professor Keyes, I
5 understand you want to go to your report.
6 But Section B.2 looks at studies related
7 to chronic patients, right?

8 A. I would need to go back
9 and -- and review all of the -- there's a
10 number of different meta-analyses in this
11 report. And so in order to answer
12 whether every single study always
13 included chronic patients I would need to
14 go back and look which I'm happy to do.

15 Q. Okay. My question is a
16 little more general though, than I think
17 that B.2 speaks to. So I'm going to ask
18 it again.

19 Do most people who are
20 prescribed opioids develop an opioid use
21 disorder?

22 MS. RELKIN: Objection.

23 MR. CIACCIO: Objection to
24 form.

1 THE WITNESS: Again, I think
2 that that evidence -- I -- I think
3 the epidemiological evidence that
4 answers that question is provided
5 in this section. And I think the
6 epidemiological evidence indicates
7 that there is risk of opioid use
8 disorder that follows a
9 dose-response pattern for both
10 acute and long-term prescriptions.

11 BY MR. HERMAN:

12 Q. Professor Keyes, I'm going
13 to ask you to please listen to my
14 question.

15 Do most people who are
16 prescribed opioids develop an opioid use
17 disorder?

18 MS. RELKIN: Objection to
19 form.

20 THE WITNESS: And the answer
21 is that there's a body of
22 epidemiological evidence that
23 underlies the answer to that
24 question, which is comprehensively

1 cited in the report, and that
2 available reviews and
3 meta-analyses indicate that 21 to
4 29 percent, on average of
5 individuals, will develop mild to
6 severe opioid use disorder and
7 that's coming from the 38 studies
8 published in Vowles 2015. And
9 it's supported by additional
10 evidence that's cited after the
11 Vowles paper came out. And that
12 8 to 12 percent will develop
13 opioid -- opioid use disorder from
14 moderate to severe.

15 That is my answer.

16 BY MR. HERMAN:

17 Q. Professor Keyes, you would
18 agree with me that the figure that you
19 keep referring to, Figure 1 on Page 13,
20 has a heading that says "Estimate of
21 Misuse, Abuse, and Addiction of Opioids
22 Among Chronic Pain Patients," right?

23 A. That is the Vowles review,
24 but there is additional evidence that's

1 cited in the report from other
2 epidemiological studies as well.

3 Q. Okay. But the percentages
4 that you were giving me right now come
5 from studies that looked at chronic pain
6 patients, correct?

7 A. Again, I would need to
8 review the other studies that are cited
9 in the report. There's a broad range of
10 studies, not just the Vowles review. And
11 the evidence is pretty consistent across
12 those studies. So I would need to -- you
13 know, if there's 200 references, I would
14 need to specifically pinpoint every
15 single patient population that was
16 evaluated.

17 Q. So -- I'm going to ask my
18 question again. Do most people who are
19 prescribed opioids develop an opioid use
20 disorder?

21 A. I think my answer is the
22 same.

23 MS. RELKIN: Note my
24 objection. Asked and answered.

1 Form.

2 BY MR. HERMAN:

3 Q. Is -- is your answer yes or
4 no to that question?

5 A. My answer is that there's a
6 body of epidemiological evidence that is
7 cited in the report that speaks to the
8 answer to that question in a broad range
9 of patient populations.

10 Q. Okay. On Page 4 of your
11 report you include a definition of
12 nonmedical use of prescription opioids,
13 correct?

14 A. Yes.

15 Q. And you define nonmedical
16 use as referring to both using
17 prescription opioids more often or longer
18 than prescribed or use of prescription
19 opioids without a prescription, right?

20 A. That's the definition that I
21 give.

22 Q. Okay. And that definition
23 would include a mom who was prescribed a
24 prescription opioid for a broken leg and

1 giving the leftover pills from your
2 prescription to her son when he sprains
3 his ankle?

4 MS. RELKIN: Objection.

5 THE WITNESS: That
6 definition referred to all
7 nonmedical use which includes
8 using more often or longer than
9 prescribed or use of prescription
10 opioids without a prescription.

11 So in your example, unless
12 the -- it depends on whether the
13 son with the broken ankle went to
14 a licensed provider.

15 BY MR. HERMAN:

16 Q. And so if the mom gave the
17 son pills from a prescription that she
18 previously had, the son's use of those
19 prescriptions would be nonmedical use?

20 A. That would be covered under
21 this definition of nonmedical use.

22 Q. Okay. And a college kid who
23 gets a prescription, shares with a
24 friend, that's nonmedical use?

1 A. You know, I think I've been
2 clear about the definition. So use of a
3 prescription opioid more often or longer
4 than prescribed or use of prescription
5 opioids without a prescription. So any
6 use of prescription opioids without a
7 prescription would fall under that
8 category.

9 Q. And also if you used a
10 prescription in a different way than the
11 doctor prescribed, correct?

12 MS. RELKIN: Objection to
13 form.

14 THE WITNESS: Again, the
15 definition is both using
16 prescription opioids more often or
17 longer than prescribed or use of
18 prescription opioids without a
19 prescription.

20 BY MR. HERMAN:

21 Q. So if someone got a
22 prescription and they were in a lot of
23 pain and they took more than directed,
24 that would be nonmedical use, correct?

1 MS. RELKIN: Objection to
2 form.

3 THE WITNESS: So the
4 definition includes more often or
5 longer than prescribed.

6 BY MR. HERMAN:

7 Q. So the answer to my question
8 is yes?

9 A. Yeah, under this definition
10 using more often or longer than
11 prescribed is covered under nonmedical
12 use.

13 Q. Are there different types of
14 prescription opioids?

15 A. Yes.

16 Q. The term "prescription
17 opioid" describes a wide range of
18 products, correct?

19 MS. RELKIN: Objection to
20 form.

21 THE WITNESS: Yes.

22 BY MR. HERMAN:

23 Q. There are differences in
24 dosages?

1 A. Yes.

2 Q. Differences in indication?

3 A. So I've listed here under
4 the definition of prescription opioids,
5 the prescription opioids that I
6 considered in the report, and they have
7 different dosages and are used for
8 different types of conditions.

9 Q. Some are long-acting?

10 A. That's correct.

11 Q. Some are immediate release?

12 A. That's correct.

13 Q. Some are combination
14 products?

15 A. There are a wide range of
16 opioid products.

17 Q. There are illicit opioids?

18 A. I'm sorry?

19 MS. RELKIN: Objection to
20 form.

21 BY MR. HERMAN:

22 Q. Are there illicit opioids?

23 A. Are there illicit opioids in
24 the world?

1 Q. Yes.

2 A. Yes, there are illicit
3 opioids.

4 Q. Heroin?

5 A. Heroin is, in the United
6 States, an illicit opioid.

7 Q. Illicit fentanyl?

8 A. There is fentanyl that is
9 both provided by physician prescription,
10 and there's also fentanyl that is
11 illicitly manufactured and sold.

12 Q. The defendants in this case
13 don't manufacture illicit opioids, right?

14 MS. RELKIN: Objection to
15 form.

16 THE WITNESS: I would have
17 to see the list of defendants in
18 the case.

19 BY MR. HERMAN:

20 Q. You are not aware of whether
21 the defendants in this case manufacture
22 illicit opioids?

23 A. So what I maintain in the
24 report is that the oversupply of

1 prescription opioids in the United States
2 that was due to understating the risks of
3 opioids to the medical community and the
4 general public at large created a system
5 in which diversion could occur and which,
6 you know, there was a large market for
7 the use of broad range of prescription
8 opioids for nonmedical uses and that
9 approximately 80 percent of individuals
10 who transition to the illicit opioids
11 that you state, began with prescription
12 opioids. So that's the opinion that's
13 stated in the report.

14 Q. Okay. And we'll get to
15 those opinions. But do defendants in
16 this case manufacture illicit opioids?

17 MS. RELKIN: Objection to
18 form.

19 THE WITNESS: So --

20 MS. RELKIN: You can answer.

21 THE WITNESS: In terms of
22 what the defendants in this case
23 do and do not manufacture, some of
24 them don't manufacture anything.

1 And so...

2 BY MR. HERMAN:

3 Q. Okay. Do any of them
4 manufacture illicit opioids?

5 A. Well, yes.

6 MS. RELKIN: Objection to
7 form.

8 THE WITNESS: In some way,
9 because the prescription opioids
10 that were manufactured were used
11 illicitly.

12 BY MR. HERMAN:

13 Q. Okay. And why don't we --
14 maybe it will help with the terminology
15 to define some stuff. I'm going to treat
16 prescription opioids as -- as licit. And
17 I understand that when they're used
18 nonmedically or without a prescription,
19 that's, in your opinion, improper. But
20 I'm going to separate those from things
21 like heroin and illicit fentanyl, which
22 I'm going to refer to as illicit opioids.
23 Can we agree on that terminology?

24 MS. RELKIN: Objection.

1 THE WITNESS: I don't agree
2 with that. I don't agree with
3 that terminology.

4 I mean, I guess my question
5 is, when you're talking about the
6 illicitness of substances, are you
7 talking about the user?

8 BY MR. HERMAN:

9 Q. I'm talking about the type.
10 So heroin --

11 A. I mean, there's prescription
12 opioids that are illicitly manufactured
13 as well. So I don't think that that
14 definition can be broadly applied.

15 Q. Okay. Would it be all right
16 with you if I referred to nonsteroidal
17 antiinflammatory drugs as you do in your
18 report as NSAIDs?

19 A. Yes.

20 MR. HERMAN: How long have
21 we been going?

22 Why don't -- why don't we
23 take a break?

24 THE VIDEOGRAPHER: The time

1 is 10:19 a.m. Off the record.

2 (Short break.)

3 THE VIDEOGRAPHER: The time
4 is 10:35 a.m. Back on the record.

5 BY MR. HERMAN:

6 Q. Professor Keyes, on -- I'm
7 going to direct you to Page 10 of your
8 report. At the very bottom of Page 10,
9 the last sentence that starts on Page 10
10 and goes onto 11, you wrote, "The supply
11 of opioids was driven by a multitude of
12 factors, including direct marketing to
13 physicians using data that was
14 underestimated (sic) use disorder risks
15 in patients."

16 Correct?

17 A. That's what I wrote.

18 Q. Did you conduct a critical
19 literature review regarding what caused
20 opioid prescribing to increase?

21 A. What I document --

22 MS. RELKIN: Form.

23 THE WITNESS: -- in the
24 report is the epidemiological

1 evidence for the increase in
2 prescribing. And I'm sorry,
3 what's the second question? Did
4 I --

5 BY MR. HERMAN:

6 Q. I think there was only one
7 question --

8 A. Okay.

9 Q. -- if you could listen.
10 Did you conduct a critical
11 literature review regarding what caused
12 opioid prescribing to increase?

13 MS. RELKIN: Objection to
14 form.

15 THE WITNESS: The -- what
16 the report indicates is that
17 prescribing did increase, and
18 those increases were associated
19 with harm. I think what I say in
20 the report, that there are a
21 multitude of factors that have
22 been documented in the
23 epidemiological literature to
24 contribute to that. But the

1 critical literature review of
2 every factor is not -- there's no
3 section in the report on that.

4 BY MR. HERMAN:

5 Q. Okay. Let's start at the
6 first part. Did you conduct a critical
7 literature review about the causes --
8 what caused opioid prescribing to
9 increase?

10 MS. RELKIN: Objection.

11 Asked and answered.

12 THE WITNESS: So what --
13 there's two parts to that
14 question, right. So one part is
15 the literature review that I
16 conducted, which I think we've
17 discussed. And the second is what
18 is covered in the report.

19 And what is covered in the
20 report is listed across each of
21 these headings. And so there is
22 literature on factors that were
23 associated with increases in
24 prescribing, and to the extent

1 that that's in the epidemiological
2 literature, it is in the report.

3 BY MR. HERMAN:

4 Q. I -- I don't think my
5 question had two parts. I just asked,
6 did you conduct a literature review
7 regarding causes of the increase in
8 opioid prescribing?

9 MS. RELKIN: Objection to
10 form. Asked and answered.

11 THE WITNESS: So again, I
12 conducted a literature review in
13 the -- throughout the report.

14 And with regard to causes of
15 why opioid prescribing increased,
16 there is epidemiological evidence
17 that is cited in the report about
18 causes of the increase in
19 prescribing.

20 BY MR. HERMAN:

21 Q. But you didn't conduct a
22 specific literature review directed at
23 determining the causes of --

24 MS. RELKIN: Objection.

1 THE WITNESS: I reviewed the
2 literature throughout the report.

3 BY MR. HERMAN:

4 Q. Okay. So is the answer to
5 my question, no, I did not conduct a
6 review of literature regarding causes of
7 the increase in opioid prescribing?

8 MS. RELKIN: Objection to
9 form.

10 THE WITNESS: So I think
11 what I said in the report is that
12 the causes of the opioid epidemic,
13 they are -- were multifactorial.
14 And throughout the report I speak
15 to the multifactorial nature of
16 those causes across a number of
17 different actors.

18 BY MR. HERMAN:

19 Q. Okay. And in the sentence
20 that begins on Page 10 and goes onto 11,
21 you mention that there were a multitude
22 of causes, correct?

23 A. That's correct.

24 Q. And what were the multitude

1 of factors that drove the supply of
2 prescription opioids?

3 A. So in describing the
4 multitude of factors that drove the
5 supply of prescription opioids, I rely on
6 the epidemiological literature, and I
7 think that is cited here. I'll point you
8 to a couple different places where I
9 review the evidence with regard to direct
10 marketing to physicians is in --

11 Q. Professor Keyes, I'm going
12 to let you finish, but that's not my
13 question.

14 A. So I'm trying to answer the
15 question. There -- you want to know the
16 multitude of factors, and so I reviewed
17 that evidence for the report and it's
18 cited in a number of different places.
19 And so to answer the question, I was
20 going to point you to the places that
21 it's cited.

22 Q. Okay. Go ahead.

23 A. Okay. Okay. So the direct
24 marketing and payments to physicians is

1 cited -- let's see. On Page 22. The
2 paragraph that starts "pharmaceutical
3 company marketing to physicians" is where
4 the evidence regarding marketing and
5 payments and associated -- there's a
6 number of citations that indicate that it
7 increased the opioid supply. That's
8 cited here.

9 Q. And does that discuss the
10 multitude of causes?

11 A. So that's among the causes.
12 And in terms of -- I'm sorry --

13 Q. You -- you only discuss what
14 you believe to be information about the
15 marketing to physicians, correct?

16 A. No, there's other --

17 MS. RELKIN: Objection.

18 THE WITNESS: Yeah, no,
19 that's -- that's incorrect.

20 There's other evidence that's
21 cited throughout here as well, in
22 terms of, you know, the increase
23 in -- the increase in the actual
24 supply.

1 BY MR. HERMAN:

2 Q. Okay. So other than
3 marketing, what are the other factors in
4 the multitude of factors that drove the
5 supply of prescription opioids?

6 MS. RELKIN: Objection to
7 form.

8 THE WITNESS: I think what
9 I've cited in this report is the
10 number of products that were
11 developed.

12 BY MR. HERMAN:

13 Q. So --

14 A. The number of opioid
15 prescription products that were
16 developed. It's cited in that very
17 paragraph.

18 So there was a number of
19 products that were developed and they
20 were marketed and the supply increased.

21 Q. Okay. So you've named two
22 factors now. What are the other factors
23 that make up the multitude of factors?

24 A. So then, I have another

1 section in the report that I'll point you
2 to that goes into other factors as well.
3 Hold on a second.

4 So Section B.8, Page 27, the
5 uptake of diverted opioids is not random
6 but part of a complex system that
7 involved community level economic
8 conditions. Discusses how -- looked at
9 prescription opioid-related distribution
10 and mortality with that was heterogenous
11 across the United States with respect to
12 economic conditions as well. So I would
13 say that would be the third part of the
14 multitude of factors.

15 Q. So economic conditions is a
16 factor that --

17 A. Explains a small portion of
18 the county level variance in
19 distribution.

20 Q. Okay. And what about desire
21 to address the undertreatment of pain?

22 MS. RELKIN: Objection to
23 form.

24 THE WITNESS: I have --

1 there's -- again, what I cite in
2 this report is the epidemiological
3 evidence. And while -- I'm -- I'm
4 just -- that's not part of the
5 epidemiological evidence that has
6 a strong evidence base.

7 BY MR. HERMAN:

8 Q. So you don't believe that
9 the desire to address the undertreatment
10 of pain was a factor that drove the
11 supply of prescription opioids?

12 MS. RELKIN: Objection to
13 form.

14 THE WITNESS: I believe that
15 what I cited in this report is the
16 strongest available
17 epidemiological evidence that
18 addresses population level
19 patterns and the desire to treat
20 undertreated pain. It's not among
21 the -- the epidemiological studies
22 that brought evidence to bear on
23 the issue.

24 BY MR. HERMAN:

1 Q. What about patient
2 satisfaction surveys, were they one of
3 the factors that drove the supply of
4 prescription opioids?

5 MS. RELKIN: Objection to
6 form.

7 THE WITNESS: Again, I --
8 what I cited in this report is, I
9 think, the epidemiological
10 evidence for the increase in
11 product distribution, sales, and
12 marketing, as well as heterogenous
13 supply across areas with different
14 economic conditions.

15 BY MR. HERMAN:

16 Q. What about changes to the
17 practice of medicine?

18 A. What about it? What's the
19 question?

20 Q. Time constraints. Do you
21 think that time constraints on doctors
22 was a factor that drove the supply of
23 prescription opioids?

24 MS. RELKIN: Objection to

1 form.

2 THE WITNESS: So again I --
3 I think I've been pretty clear
4 about what's in the report in
5 terms of the factors that I
6 evaluated in the epidemiological
7 literature. These are the studies
8 that I relied on to form my
9 opinions.

10 BY MR. HERMAN:

11 Q. What about the overall
12 increase in the use of all prescription
13 medications?

14 A. Again, what I -- what I
15 cited in the -- in the epidemiological
16 literature are the factors that are in
17 the report.

18 Q. And did you -- again, did
19 you go out and look for epidemiological
20 literature that discussed causes of the
21 opioid -- increase in opioid supply?

22 MS. RELKIN: Objection to
23 form.

24 THE WITNESS: I can keep an

1 open mind with respect to levels
2 of evidence and sources of
3 evidence and where they are drawn
4 from.

5 BY MR. HERMAN:

6 Q. Did you run searches
7 specifically to look at the causes of
8 factors that -- excuse me. Let me
9 rephrase that question.

10 Did you run searches
11 specifically to look at the factors that
12 drove the increase in supply of
13 prescription opioids?

14 MS. RELKIN: Objection to
15 form.

16 THE WITNESS: That already
17 was asked. And, again, I think I
18 did a literature review and the
19 topics of the literature review
20 are listed in the report.

21 BY MR. HERMAN:

22 Q. So is the answer to my
23 question, no, you did not specifically
24 run searches to look at what factors

1 drove the increase in supply of
2 prescription opioids?

3 A. What I reviewed in the
4 report was the epidemiological literature
5 around the causes of the opioid epidemic
6 and so, in doing so, I reviewed
7 literature from a wide variety of
8 epidemiological studies.

9 Q. And, again, did you
10 specifically look for literature that
11 addressed the causes of the increase in
12 supply of prescription opioids?

13 MS. RELKIN: Objection to
14 form.

15 THE WITNESS: I've cited a
16 number of epidemiological studies
17 that have examined the causes of
18 the increase in supply in the
19 report.

20 BY MR. HERMAN:

21 Q. Professor Keyes, I would ask
22 that you listen to the question that I'm
23 asking.

24 A. Okay.

1 Q. And I asked, did you
2 specifically look for literature that
3 addressed the causes of the increase in
4 supply of prescription opioids?

5 A. I think I've --

6 MS. RELKIN: Objection.

7 THE WITNESS: -- addressed
8 that in the report. I
9 specifically looked at the body of
10 literature that I was asked to
11 evaluate. And within that
12 literature there are a number of
13 epidemiological studies that
14 examine oversupply of opioids as
15 the product of marketing and
16 payments to physicians as one
17 component.

18 The increase in the number
19 of products is another component,
20 and heterogenous distribution
21 across economic regions. Excuse
22 me.

23 BY MR. HERMAN:

24 Q. Okay. And you're not aware

1 of literature that discusses the
2 undertreatment of pain as a factor that
3 drove the supply of prescription opioids?

4 MS. RELKIN: Objection to
5 form.

6 THE WITNESS: What I said in
7 the report is the epidemiological
8 evidence.

9 BY MR. HERMAN:

10 Q. And you're not aware of
11 literature that discusses the increase in
12 use of all prescription medications as a
13 factor that drove the increase in supply
14 of prescription opioids?

15 A. The increase in the supply
16 of opioids was -- I cite in the report
17 what the increases in the supply of
18 opioids was. And my report covers the
19 increase in supply of opioids.

20 Q. Okay. All right. I'm going
21 to ask you to flip to Page 3. The first
22 bullet on that page, it's your opinion
23 that the expansion of nonmedical
24 prescription opioid use would not have

1 occurred without the widespread
2 availability of prescription opioids that
3 were originally dispensed for medical
4 uses, often in greater quantities and
5 doses than needed, leaving a surplus of
6 opioids that could be diverted for
7 nonmedical uses, correct?

8 A. That's what's written, yes.

9 Q. And that's your opinion?

10 A. Yes.

11 Q. And when you say that
12 prescription opioids were dispensed for
13 medical uses, what do you mean?

14 A. Okay. So I say here the
15 expansion of nonmedical prescription
16 opioid use would not have occurred
17 without the widespread availability that
18 were originally dispensed for medical
19 uses. So these were prescriptions
20 obtained by a doctor or a dentist or
21 other licensed provider.

22 Q. Legitimate prescriptions for
23 medical use -- let me rephrase that
24 question. What you're saying in this

1 bullet point is that increases in supply
2 due to legitimate prescriptions for
3 medical use created the opportunity for
4 diversion?

5 A. I said they're dispensed for
6 medical use.

7 Q. Okay. Let me just finish my
8 question. Let's try to get on the same
9 page.

10 You're saying in this bullet
11 that the increase in supply due to
12 legitimate prescriptions for medical use
13 created the opportunity for diversion?

14 MS. RELKIN: Objection to
15 form.

16 THE WITNESS: That's not
17 what the bullet point says.

18 BY MR. HERMAN:

19 Q. Okay. That's not a fair
20 summary, that the increase in supply due
21 to legitimate prescriptions for medical
22 use created the opportunity for
23 diversion?

24 A. That's not a summary of what

1 my opinion is. I think the summary of my
2 opinion is in the bullet. The expansion
3 of nonmedical prescription opioid use
4 would not have occurred without the
5 widespread availability of prescription
6 opioids that were originally dispensed
7 for medical uses.

8 Q. Okay. So the increase in
9 supply is caused by legitimate
10 prescriptions for medical use, correct?

11 MS. RELKIN: Objection to
12 form.

13 THE WITNESS: So, right,
14 I -- I say they are dispensed for
15 medical use. And I think we've
16 covered that the legitimacy of the
17 dispensing is based on a set of --
18 of criteria that were -- materials
19 that were provided to physicians
20 that underestimated the risk. And
21 I want to correct earlier when I
22 said overestimated. That was
23 overestimated benefits. And I
24 was -- hadn't had enough tea yet.

1 BY MR. HERMAN:

2 Q. Okay. But the doctors,
3 based on the information available to
4 them were writing the prescriptions for
5 legitimate --

6 A. They were dispensed for
7 medical uses.

8 Q. Okay. And that increase in
9 supply of prescription opioids for
10 medical uses created the opportunity for
11 diversion?

12 A. And left a surplus of
13 opioids that could be diverted for
14 nonmedical uses.

15 Q. Let's just step back for a
16 moment and discuss how people obtain a
17 prescription for medical use. Okay?

18 To legally obtain a
19 prescription opioid, a person needs to
20 meet with the prescriber, correct?

21 MS. RELKIN: Objection to
22 form.

23 THE WITNESS: It -- I mean,
24 regulations on face-to-face

1 contact with a physician have
2 changed over time.

3 BY MR. HERMAN:

4 Q. When people get a
5 prescription opioid, are they supposed to
6 meet face to face with their doctor?

7 A. I'm not a medical doctor. I
8 don't -- so I would focus on the
9 epidemiological evidence.

10 Q. Okay. Let's just talk about
11 prescriptions generally.

12 When you go to get a
13 prescription, do you meet face to face
14 with your doctor?

15 MR. CIACCIO: Objection.

16 MS. RELKIN: Objection to
17 form.

18 MR. CIACCIO: She shouldn't
19 have to answer questions about her
20 practice. You said you go to your
21 doctor. If you want to rephrase
22 it, but asking her her practice
23 when she sees a doctor and what
24 prescriptions she --

1 THE WITNESS: There's a wide
2 range of ways that people obtain
3 prescriptions.

4 MR. CIACCIO: Well, I'm just
5 saying, don't ask her what she
6 does when she sees a doctor.

7 MR. HERMAN: Got it. Thank
8 you.

9 BY MR. HERMAN:

10 Q. Professor Keyes, is it your
11 conclusion that doctor shopping was rare?

12 MS. RELKIN: Objection to
13 form.

14 THE WITNESS: So I address
15 that point in the report. And I
16 would just want to point you to
17 that section to be comprehensive.

18 BY MR. HERMAN:

19 Q. On Page 18.

20 A. Well, I address it in a
21 number of different epidemiological
22 studies that have examined that issue.

23 Q. But on Page 18.

24 MS. RELKIN: She's

1 answering.

2 BY MR. HERMAN:

3 Q. All right. Go ahead.

4 A. Yeah, so on Page 18 I state,
5 "A small proportion of individuals using
6 opioids chronically receive prescriptions
7 from multiple providers and pharmacies
8 and have been characterized as doctor
9 shoppers or opioid shoppers."

10 There's a study in 2014 that
11 provides some evidence as to the
12 commonality or rareness of that practice.
13 That's McDonald and Carlson. And it was
14 concluded in that study, it remained rare
15 across states with a mean of .7 per
16 thousand individuals.

17 Q. So is your answer yes, I
18 concluded that doctor shopping was rare?

19 A. I concluded that -- what I
20 stated in the report, that the
21 epidemiological evidence indicates that
22 doctor shopping was a relatively rare
23 contribution to the overall distribution
24 and prescribing of opioids.

1 Q. And is that your opinion
2 with respect to Summit County?

3 A. With regard to Summit
4 County, I have not --

5 MS. RELKIN: Objection to
6 form.

7 THE WITNESS: -- the study
8 did not examine Summit County in
9 particular.

10 And so when thinking about
11 how to generalize those studies
12 across many counties there's a
13 number of different considerations
14 that we could keep in mind.

15 So all of the data I have on
16 Summit County I've cited in the
17 report in the latter section.

18 BY MR. HERMAN:

19 Q. Okay. Is it your opinion
20 that pill mills do not explain in any
21 significant way the expansion of opioid
22 prescribing and opioid-related harms in
23 the U.S.?

24 A. That is also cited in this

1 section. And I cite evidence here that
2 indicates that there are some specialties
3 of medicine that have more concentrated
4 prescription practice. But actually if
5 you look at almost every specialty,
6 including general practitioners, that
7 there was an increase in opioid
8 prescriptions.

9 So based on that evidence,
10 you know, well, certainly there were
11 rogue prescribers, there was just a
12 general increase across all prescribers,
13 across the broad majority of prescribers.

14 Q. But is it your opinion that
15 pill mills do not explain in any
16 significant way the expansion of opioid
17 prescribing and opioid-related harms in
18 the United States?

19 MS. RELKIN: Objection to
20 form. Asked and answered.

21 THE WITNESS: Yeah, again, I
22 would point -- my -- my answer to
23 that is that the epidemiological
24 evidence indicates that there were

1 rogue prescribers and pill mills.
2 But that the entirety of the
3 distribution, an increase in
4 opioid supply, places those rogue
5 prescribers at a minority of the
6 distribution.

7 BY MR. HERMAN:

8 Q. Okay. And that's helpful, I
9 think. You're drawing a distinction
10 between rogue prescribers and prescribers
11 engaged in medical practice?

12 MS. RELKIN: Objection to
13 form.

14 THE WITNESS: So there's
15 been a number of different
16 definitions, I guess, of these
17 sort of like rogue prescribers and
18 pill mills in the -- in the
19 available literature. And so I
20 think, as they have been
21 described, you know, prescribers
22 that are engaging in illegal trade
23 for opioids would be a separate
24 category than general medical,

1 general medical practice.

2 BY MR. HERMAN:

3 Q. Okay. And -- and I think to
4 help me going forward. That's what I'm
5 trying to get at, sort of the distinction
6 between people who were pill -- rogue
7 prescribers engaged in prescribing for
8 illegitimate means, that's -- that's the
9 rogue prescribers you're talking about in
10 this paragraph, correct?

11 A. No. I mean, again I -- I
12 wouldn't say that all prescriptions for
13 illegitimate means are from rogue
14 prescribers. I guess that's where I
15 disagree with that characterization. But
16 I do believe there are rogue prescribers.
17 I mean, I think there's evidence to
18 indicate that there are rogue
19 prescribers.

20 Q. Okay. But in this paragraph
21 and in your report, you're saying that
22 rogue prescribers did not contribute in a
23 significant way to expansion of opioid
24 prescribing and opioid-related harms in

1 the United States?

2 A. What I'm saying in the
3 report is that if you look at the overall
4 increase in the opioid supply and
5 distribution across all specialties of
6 medical practice, there are certainly
7 specialties that have a more concentrated
8 set of prescription practices. Then
9 there are also pill mills, rogue
10 prescribers.

11 But if you look at the
12 overall increase in the prescription
13 opioid distribution, it cannot be
14 accounted for by a small number of --
15 relatively small number of rogue
16 prescribers in comparison to the overall
17 increase.

18 Q. What it's accounted for
19 is -- what -- what accounts for it --
20 I -- I think I understand what you're
21 saying.

22 The overall prescribing,
23 increase in supply is accounted for by
24 prescribers engaged in the practice of

1 medicine, like general practitioners,
2 correct?

3 MS. RELKIN: Objection to
4 form.

5 THE WITNESS: That's not
6 exactly what I said. I -- I think
7 what I've stated in the opinion is
8 that the overall supply and
9 distribution and -- of opioids
10 increased -- the -- the amount of
11 the increase crossed a wide
12 variety of medical specialties.
13 And so, rogue prescribers and pill
14 mills that are explicitly
15 characterized as such account for
16 a small proportion of the
17 increase. That's my opinion.

18 BY MR. HERMAN:

19 Q. Okay. And the increase in
20 medical supply of prescription opioids is
21 what spawned what you've described as the
22 opioid epidemic?

23 A. I'm sorry, can you restate
24 the question?

1 Q. Just going back. It might
2 be helpful to go back to Bullet 3.

3 A. Okay.

4 Q. What you're saying is the
5 increase in medical supply of
6 prescription opioids is what spawned what
7 you've described as the opioid epidemic?

8 A. I said that the expansion of
9 nonmedical use would not have occurred
10 without that increase in the opioid
11 supply dispensed for medical use.

12 Q. Okay. And so if I'm
13 understanding you correctly, it's your
14 opinion that prescriptions written for
15 medical use were the significant cause of
16 the increase in opioid supply and in
17 turn -- and in turn, the opioid epidemic?

18 A. I'm sorry, I'm just going to
19 read this again.

20 MS. RELKIN: Objection to
21 form.

22 THE WITNESS: I'm going to
23 read it back to make sure I
24 understand the question.

1 "It is your opinion that
2 prescriptions written for medical
3 use were the significant cause of
4 the increase in opioid supply and
5 in turn the opioid epidemic."

6 Again, I think what I've --
7 what I've documented in the report
8 is that doctors and other medical
9 professionals were dispensing
10 opioids, were misinformed about
11 the risks and benefits of those
12 medications. So to say that
13 prescriptions written for medical
14 use were the significant cause of
15 the increase in the opioid supply
16 I think is too simplistic for what
17 generated the opioid epidemic.

18 BY MR. HERMAN:

19 Q. And -- but what I -- when
20 you say these doctors were misinformed --
21 strike that.

22 The doctors who were
23 dispensing the prescription opioids
24 believed they were giving them to their

1 patients for legitimate medical needs,
2 correct?

3 MS. RELKIN: Objection to
4 form. Overbroad.

5 THE WITNESS: I can't speak
6 to every doctor who wrote a
7 prescription for an opioid. And
8 what they believed and what they
9 didn't.

10 BY MR. HERMAN:

11 Q. They believed that they were
12 writing the prescription for medical
13 uses?

14 MS. RELKIN: Objection.

15 THE WITNESS: Again, I -- I
16 can't speak for every doctor.

17 BY MR. HERMAN:

18 Q. In Bullet 3 though, aren't
19 you saying that prescription opioids that
20 were originally dispensed for medical
21 uses, so --

22 A. What I say in Bullet 3 is
23 that the expansion of nonmedical
24 prescription opioid use would not have

1 occurred without the widespread
2 availability of prescription opioids that
3 were originally dispensed for medical
4 uses.

5 Q. And when you say dispensed,
6 you mean prescribed by doctors, correct?

7 A. So I say -- I think what I
8 say here is just dispensed for medical
9 uses, whoever the prescriber is.

10 Q. When you -- when you use the
11 word dispensed, what do you mean?

12 A. I mean when they are
13 prescribed for medical use.

14 Q. If you could go to Page 17.
15 I just want to ask you a couple more
16 questions about Page 18.

17 A. 18 or 17?

18 Q. 18.

19 A. 18.

20 Q. Professor Keyes, do you
21 believe that doctor shopping -- let me
22 rephrase that question.

23 Professor Keyes, is it your
24 opinion that doctor shopping was not a

1 significant cause of what you have
2 described as the opioid crisis?

3 MS. RELKIN: Objection to
4 form.

5 THE WITNESS: I feel like
6 we've addressed this. I think
7 Citation Number 48, we can go
8 through the data that's used in
9 that study. But that study in
10 particular concluded that doctor
11 shopping is associated with the
12 overall prevalence of opioid
13 prescribing, but that overall it
14 remained rare across states.

15 So there is an overall
16 increase across all these
17 different sectors, and that
18 overall increase -- and there's a
19 minority of that overall increase
20 that's due to doctor shopping.

21 BY MR. HERMAN:

22 Q. Okay. And is the same true
23 that there's a minority of the increase
24 in the overall opioid supply that is due

1 to rogue prescribers?

2 A. I'm sorry. I'm going to
3 have to read that again.

4 MS. RELKIN: Object to form.

5 THE WITNESS: And is the
6 same true that minority of the
7 increase of the overall opioid
8 supply that is due to rogue
9 prescribers?

10 So again, I would point to
11 References 48 and 49 which I think
12 speak to that topic that have
13 concluded that you know --
14 Reference 49, for example, that
15 prescribing of opioids increased
16 across many specialties in
17 medicine.

18 So you know, a small number
19 of high-volume prescribing
20 facilities did not cause the
21 opioid epidemic. It was broader
22 in scope.

23 BY MR. HERMAN:

24 Q. Okay. And on Page 17,

1 second paragraph you wrote, "Data on the
2 diversion of opioids are drawn from a
3 variety of sources. All data sources
4 have found that prescription opioid
5 diversion is common, especially unused
6 prescriptions that were over prescribed
7 to family and friends of nonmedical
8 users." Correct?

9 A. That is what is written.

10 Q. And is that what you're
11 discussing in the third bullet point of
12 your opinions when you say that medical
13 prescriptions in greater doses and
14 quantities than necessary created a
15 surplus prescription opioid -- surplus of
16 prescription opioids that could be
17 diverted for nonmedical uses?

18 A. I'm discussing the whole
19 section. The entire section that begins
20 on Page 16 with B.3.

21 So it's -- that's a number
22 of different studies that are cited in
23 the overall section, and that's one
24 sentence.

1 Q. Do the studies that you cite
2 consistently show that the largest
3 percentage of nonmedical users obtain
4 their prescription opioids from family
5 and friends?

6 MS. RELKIN: Objection to
7 form.

8 THE WITNESS: So there's a
9 number of different studies that
10 have examined sources of
11 prescription opioids among
12 nonmedical users.

13 And I would point -- so
14 there's a number of different
15 references that I cite in here.

16 In that paragraph, I'm
17 mostly talking about the
18 prescriptions that are obtained
19 from friends or family, which
20 again is driven by the oversupply.

21 In the next paragraph, I
22 also talk about the number of
23 nonmedical users who -- the
24 studies that demonstrate the high

1 proportion of nonmedical users
2 that do obtain their opioids from
3 legitimate prescribers.

4 So there's -- there's
5 multiple sources of nonmedical
6 prescription opioids. Some is
7 from family and friends due to
8 oversupply. Some are from medical
9 prescriptions that may have begun
10 with a medical condition and
11 continued on to nonmedical use.
12 There's a number of different ways
13 that people begin their nonmedical
14 opioid using -- use.

15 BY MR. HERMAN:

16 Q. Professor Keyes, do you
17 agree, though, that the studies that you
18 cite consistently show that the largest
19 percentage of nonmedical users obtain
20 their prescription opioids from family
21 and friends?

22 MS. RELKIN: Objection to
23 form.

24 THE WITNESS: No. I don't.

1 That's not what is cited in this
2 opinion.

3 For example, if you look at
4 Shei 2015, among individuals of
5 opioid abuse or dependence, 79.9
6 had at least one claim for a
7 prescription opioid prior to their
8 diagnosis. So there's a number of
9 different studies with a number of
10 different study designs and a
11 number of different populations.

12 And in that you'll find
13 heterogenous plethora of estimates
14 of the sources of nonmedical
15 prescription opioids.

16 BY MR. HERMAN:

17 Q. And so let me --

18 A. Cicero and colleagues 2011
19 is another example. They found that
20 50 percent of almost 2,000 individuals in
21 treatment for opioid dependence reported
22 that doctors were among the various
23 methods for obtaining opioids.

24 Q. Okay. Let's look at what

1 I'm going to mark as Exhibit 3.

2 (Document marked for
3 identification as Exhibit
4 Keyes-3.)

5 MS. RELKIN: Take as much
6 time as you need to review it.

7 BY MR. HERMAN:

8 Q. And Professor Keyes, this is
9 one of the sources that you cite in
10 Section B.3 of your report, correct?

11 A. I'm just going to find
12 the -- do you know what number citation
13 it is in my report?

14 Q. I believe it is 41.

15 A. I would just like to find
16 the section where it is cited. So this
17 is 41, "Data from the National Household
18 Survey on Drug Use and Health from
19 2013-2014 indicate that among nonmedical
20 opioid users interview, 50.5 percent
21 report from a friend or relative."

22 Q. And so, Professor Keyes,
23 before you read me your whole report --

24 A. That's all right.

1 Q. -- I'm going to ask you some
2 questions about the exhibit.

3 If I could ask you to turn
4 to Page 2, please.

5 Okay. And Figure 1 shows
6 sources of prescription pain relievers
7 for the most recent nonmedical use among
8 past year users age 12 and older,
9 correct?

10 A. I'm going to need a moment
11 to review the -- I mean, I have 200
12 citations in my -- I just need a minute
13 to read what I'm talking about. Okay.

14 Q. Okay. And as you just read
15 from your report, this figure shows that
16 50 percent -- 50.5 percent obtained from
17 a friend or relative for free?

18 A. So what --

19 MS. RELKIN: Objection.

20 THE WITNESS: -- is
21 documented in Figure 1, just so
22 we're clear about what these data
23 show, is among those who misuse
24 prescription pain relievers, as

1 they refer to it in the study,
2 they were identified where the
3 prescription pain relievers they
4 had most recently misused. That
5 is not their total -- sum total of
6 misuse. But what this article is
7 specifically talking about is
8 where they most recently misused.
9 And yes, the 50.5 percent most
10 recently misused from a friend or
11 relative for free.

12 BY MR. HERMAN:

13 Q. And another 11 percent
14 bought from a friend or relative?

15 A. So in terms of documenting
16 the modal sources of most recent
17 nonmedical use, 50.5 were from a relative
18 for free, 22.1 percent were from one
19 doctor, and then the next lowest
20 percentage is bought from a friend or
21 relative, 11 percent.

22 Q. And then after that is took
23 from a friend or relative without asking,
24 and that was 4.4 percent?

1 A. That's correct.

2 Q. And then bought from drug
3 dealer or other stranger, 4.8 percent?

4 A. Mm-hmm.

5 Q. Okay. And then from more
6 than one doctor, that's 3.1 percent?

7 A. That's what's listed here.

8 Q. Okay. And so at least based
9 on this information in this study, it's
10 consistent with what I said before that
11 not the majority of people obtain at
12 least their most recent prescription
13 opioid that they use for nonmedical
14 reason from a family member or friend?

15 MS. RELKIN: Objection to
16 form.

17 THE WITNESS: What this
18 study assessed is among
19 nonmedical -- nonmedical
20 prescription pain -- pain reliever
21 users, the source that they most
22 recently misused. It does not
23 describe the totality of all of
24 the sources that they ever

1 received a nonmedical prescription
2 opioid from, and with that caveat,
3 from 2013 to 2014, what Figure 1
4 shows is that among nonmedical
5 prescription opioid users in this
6 sample, the most recent
7 prescription opioid misuse was
8 50.5 percent from a friend or
9 relative for free.

10 BY MR. HERMAN:

11 Q. And on Page 17 of your
12 report you write, "Given that close to
13 98 million Americans received
14 prescription pain relievers each year,
15 much larger number than the estimated
16 12.5 million who use opioids
17 nonmedically, the contribution of
18 diversion through sources such as friends
19 and family for nonmedical use as a small
20 portion of the overall expansion of the
21 opioid supply and result in
22 opioid-related harm."

23 In the first part of that
24 sentence, you're saying that a lot more

1 people are prescribed opioids and use
2 them medically than the number of people
3 who use prescriptions nonmedically,
4 correct?

5 A. I say 98 percent --
6 98 million Americans receive prescription
7 pain relievers and that's a larger number
8 than the 12.5 million who use
9 nonmedically, correct.

10 Q. Okay. And in the second
11 part of the sentence is your point that
12 diversion involves a much smaller portion
13 of the prescription opioid supply than
14 medical use of prescription opioids?

15 A. I'm sorry, I have to read
16 that again.

17 In the second part of the
18 sentence your point, diversion involves a
19 smaller proportion of the opioid supply
20 than medical use of prescription opioids.

21 MS. RELKIN: Objection.

22 THE WITNESS: No, that's not
23 what the sentence says. It says
24 that the contribution of diversion

1 through sources such as family and
2 friends for nonmedical use is a
3 small proportion of the overall
4 expansion in the supply.

5 BY MR. HERMAN:

6 Q. Okay. Okay. Can we turn to
7 Page 16. And at the -- in the last
8 sentence on Page 16 that goes onto
9 Page 17, what do you mean when you say
10 prescription opioids are diverted from
11 medical facilities?

12 A. Okay. Hold on one second.
13 So this is Section B.3, "Opioids were
14 diverted and used by individuals with
15 opioid use disorder for nonmedical use."

16 So then, I have -- I
17 reviewed evidence for opioid use disorder
18 after medical use, "however an additional
19 consequence of the increased supply was
20 opioid diversion. That is, the evidence
21 shows that prescription opioids are
22 diverted from the supply chain from
23 medical facilities and pharmacies for
24 sale to the black market for distribution

1 and sale for nonmedical uses."

2 So -- I'm sorry, I just
3 needed to orient myself to what it says.

4 Q. Take your time.

5 A. So then the question is what
6 did I mean by medical facilities?

7 Q. What do you mean when you
8 say that prescription opioids are
9 diverted from medical facilities?

10 A. I was speaking there broadly
11 to the definition of diversion that I
12 gave on Page 5. I'm sorry. Diversion is
13 defined on page 6.

14 "Diversion of opioids has
15 been defined in various ways."

16 I use a broader definition
17 of diversion which is consistent with
18 numerous other scholars. Opioids that
19 are diverted from the intended recipient
20 is what I use as the definition of
21 diversion. So diversion from the supply
22 chain from medical facilities would be
23 any use of opioids that was not among
24 their intended recipient.

1 Q. Are you aware of diversion
2 from any specific pharmacy in Cuyahoga
3 County?

4 MS. RELKIN: Objection.
5 Form.

6 THE WITNESS: I was asked to
7 do an epidemiological review of
8 the evidence that I was -- that I
9 cite in the report.

10 BY MR. HERMAN:

11 Q. So is the answer no, you're
12 not aware of any diversion from any
13 specific pharmacy in Cuyahoga County?

14 MS. RELKIN: Objection.

15 THE WITNESS: My report is
16 on the epidemiological evidence
17 for the opioid epidemic.

18 BY MR. HERMAN:

19 Q. Are you aware of diversion
20 from any specific pharmacy in Summit
21 County?

22 MS. RELKIN: Same objection.

23 THE WITNESS: So I have data
24 on the Cuyahoga and Summit County

1 in terms of population totals.
2 But in -- in epidemiological scope
3 of the opioid epidemic is a
4 population level aggregate data
5 summary of what occurred in the
6 United States, and to the degree
7 that I have data that I can speak
8 to the counties in terms of
9 overdose risk, in terms of needs
10 assessments, I have included those
11 data in this report.

12 BY MR. HERMAN:

13 Q. So you are not aware of
14 diversion from any specific pharmacy in
15 Summit County?

16 MS. RELKIN: Objection to
17 form. And asked and answered.

18 THE WITNESS: I'm an
19 epidemiologist, and what is
20 included in this report is the
21 epidemiology of opioid use
22 disorder and the broad range of
23 topics that I was asked to cover
24 in this report.

1 BY MR. HERMAN:

2 Q. Okay. Professor Keyes, I'd
3 ask that you answer the questions that
4 I'm actually asking. So I'm going to ask
5 it one more time.

6 So are you aware of
7 diversion from any specific pharmacy in
8 Summit County?

9 A. Again, I would point to what
10 I was asked to cover in my report, which
11 is aggregate level data on the opioid
12 epidemic.

13 Q. What's your understanding of
14 the supply chain for prescription
15 opioids?

16 A. Can you be more specific in
17 terms --

18 Q. Well, you wrote, "The
19 evidence shows that prescription opioids
20 are diverted from the supply chain." So
21 I'm asking you what is your understanding
22 of the supply chain as you used it in
23 that sentence.

24 A. So the way I use supply

1 chain in that sentence was any point
2 along the -- the route that an opioid
3 would take to a user. The -- the
4 specific ins and outs of the supply chain
5 are not part of the epidemiological body
6 of evidence that I reviewed.

7 Q. What's your evidence that
8 shows that prescription opioids are
9 diverted from the supply chain for sale
10 to the black market?

11 MS. RELKIN: Objection to
12 form.

13 THE WITNESS: So I would
14 point to -- I mean we can use the
15 exhibit that you provided to me or
16 we can use the other studies that
17 I cited in the report, that form
18 the basis of that opinion which
19 are about where users obtain their
20 opioids. And many of them are
21 obtained from -- not many, but a
22 portion are obtained from the
23 black market. And the ways in
24 which opioids get to the black

1 market have been documented in
2 those references as well.

3 BY MR. HERMAN:

4 Q. Are any of the categories
5 listed on Figure 1 in Exhibit 3, part of
6 the supply chain?

7 A. I would say all of them are
8 part of the supply chain.

9 Q. Friends and family are part
10 of the supply chain?

11 A. The friends and family were
12 supplied with opioids.

13 Q. Are they -- so you're --
14 you're defining the supply chain to
15 include the person that actually receives
16 the prescription?

17 A. I think my use of that
18 statement in that sentence referred to an
19 overall understanding of the way in which
20 opioids are routed to users.

21 Q. So are you saying that the
22 diversion occurs within the supply chain
23 or after the prescription opioids leave
24 the supply chain?

1 MS. RELKIN: Objection to
2 form.

3 THE WITNESS: I think what
4 I've cited in this section is what
5 the epidemiology of diversion,
6 which I have defined on again
7 Page 4, I think Page 4, as use
8 other than the intended recipient,
9 right?

10 So based on that definition,
11 I have reviewed in this section
12 the epidemiological studies that
13 document how diversion occurs.
14 And that's based on a number of
15 different sources.

16 And the way in which
17 individuals receive opioids to use
18 nonmedically come from a
19 heterogenous group of sources, as
20 is written on Page 17.

21 BY MR. HERMAN:

22 Q. How do you define
23 oversupply?

24 A. I just want to refer to my

1 definitions to see if there is a
2 definition of oversupply. I don't
3 believe that there is in the definitions
4 section.

5 When I refer to oversupply
6 based on how it is used in the scientific
7 literature -- and I just want to pause to
8 make sure I get the scientific literature
9 correct on this -- or my understanding of
10 the scientific literature.

11 Typically, oversupply is
12 used in epidemiological studies to refer
13 to more supply than is necessary.

14 Q. Can you quantify oversupply?

15 MS. RELKIN: Objection.

16 THE WITNESS: Quantify it in
17 terms of?

18 BY MR. HERMAN:

19 Q. Let me ask it this way.

20 Would it be 90 percent less prescription
21 opioids?

22 MS. RELKIN: Objection to
23 form.

24 THE WITNESS: So when we

1 evaluate the epidemiological
2 literature, what we are evaluating
3 is the multitude of factors, as
4 we've discussed, that contribute
5 to the increase in a particular
6 health outcome. So attributing
7 percentages to one factor versus
8 another negates the way in which
9 the factors interact with each
10 other: So that's not what the
11 epidemiological literature that
12 I've assessed would allow in terms
13 of a percentage.

14 BY MR. HERMAN:

15 Q. So you can't say how much
16 the oversupply --

17 MS. RELKIN: Objection.

18 THE WITNESS: That's not
19 what I said. What I said is that
20 that's not what the
21 epidemiological literature -- what
22 the epidemiological literature
23 indicates is that there was an
24 interaction of factors across

1 multiple different levels that all
2 contributed to more opioids
3 available than were medically
4 necessary. And I think there's
5 ample epidemiological evidence to
6 support that statement. Because
7 of the interaction among all the
8 different actors that form that
9 system, attributing a specific
10 percentage is not what the
11 epidemiological literature is
12 designed to produce.

13 BY MR. HERMAN:

14 Q. What are the actors that
15 form the system that -- are you referring
16 to?

17 A. Can you be more specific?

18 Q. Well, you said interaction
19 among all the actors that form the
20 system. What are the actors that form
21 the system?

22 A. So I think I have kind of --
23 that's what the entire report is about,
24 you know. It --

1 Q. Can you name the actors that
2 form the system?

3 A. I think -- they are
4 mentioned throughout the report. I mean
5 there's not a -- it's a --

6 Q. Well, I'm just asking you
7 sitting here today, can you tell me the
8 actors that form the system?

9 MS. RELKIN: Objection to
10 form.

11 THE WITNESS: That's what
12 the entire -- the entire report
13 lists all of the -- not even all
14 of -- a large component of the
15 individuals who contributed, or
16 the individuals, the institutions,
17 and the other factors that
18 contributed to the epidemic. So I
19 think it's that's what -- that's
20 what the report is about, is --

21 BY MR. HERMAN:

22 Q. Can you just tell me who the
23 actors are that you're speaking about?

24 A. Do you want to go page by

1 page? I mean, we can --

2 Q. I'd prefer if you could -- I
3 mean, you spent all this time --

4 A. It's not a two-minute
5 answer. It's like a 30-minute answer.
6 But we can --

7 Q. Well, I'm just asking for a
8 name, a list of the people, the actors.

9 A. Right. Again --

10 MS. RELKIN: Form.

11 THE WITNESS: -- we can go
12 page by page. It's a --

13 BY MR. HERMAN:

14 Q. I'm not asking -- but
15 sitting here today, from memory, you
16 can't tell me who the actors --

17 A. I could. It's just --

18 MS. RELKIN: Objection.
19 Argumentive.

20 THE WITNESS: Right. It's
21 a --

22 BY MR. HERMAN:

23 Q. Okay. I'm going to direct
24 you to Page 18 above B.4.

1 Before we get to that, are
2 you aware that the DEA sets quotas for
3 the production of prescription opioids?

4 MS. RELKIN: Objection to
5 form.

6 THE WITNESS: I am familiar
7 with the way that that system has
8 evolved over time in terms of the
9 DEA's involvement. But my
10 particular area of expertise is
11 not in DEA enforcement.

12 BY MR. HERMAN:

13 Q. Okay. So are you aware that
14 DEA sets quotas for the production of
15 prescription opioids?

16 MS. RELKIN: Objection to
17 form.

18 THE WITNESS: I'm generally
19 aware of the DEA's involvement.
20 But I don't have any particular
21 expertise on DEA's regulations and
22 enforcement.

23 BY MR. HERMAN:

24 Q. Are you aware each

1 manufacturer is provided a specific
2 quota?

3 MS. RELKIN: Objection to
4 form.

5 THE WITNESS: Can you say
6 that again.

7 BY MR. HERMAN:

8 Q. Are you aware each
9 manufacturer is provided a specific
10 quota?

11 MS. RELKIN: Same objection.

12 THE WITNESS: Again, I'm
13 generally familiar with the --
14 that the DEA has some regulations
15 and enforcement, but I was not
16 asked to review specific
17 manufacturers' quotas and
18 whether -- the validity of them.
19 So I'm generally aware that there
20 are DEA regulations and
21 enforcement that involve
22 manufacturers, and I -- I have not
23 been asked to review the specifics
24 of each manufacturer.

1 BY MR. HERMAN:

2 Q. Okay. And going to Page 18,
3 what do you mean when you say that
4 diversion is especially problematic and
5 well documented among end users?

6 A. Can you point me to that?

7 Q. It's the last paragraph
8 right above the start of Section B.4?

9 A. "So in summary, diversion of
10 opioids has been fueled by their
11 oversupply, occurs all along the supply
12 chain, and is especially problematic and
13 well documented among end users, that is,
14 among individuals with nonmedical use or
15 opioid use disorder who report that
16 friends and family members serve as
17 sources of their opioids."

18 So I think what I have in
19 that section relatively well documents
20 that there's a substantial portion of
21 nonmedical opioid use that occurs due to
22 family and friends trading supply due to
23 their oversupply.

24 Q. The medical oversupply that

1 we talked about earlier?

2 A. Given that there are more
3 prescription opioids available than are
4 needed, it facilitates a diversion market
5 in which friends and family trade
6 prescription opioids.

7 Q. And I just want to make sure
8 we're on the same page. When you say
9 more than are needed, we're referring to
10 the more than are needed for the medical
11 use that they were originally prescribed
12 for?

13 A. I'm not speaking to each
14 individual prescription. I'm saying
15 overall, what the epidemiology shows is
16 that there was an exponential increase in
17 the supply of opioids that created an
18 oversupply than what is medically needed
19 at a population level.

20 Q. Okay. And --

21 A. And at a population level
22 you can also document that individuals
23 receive prescription opioids from family
24 and friends across all of these sources.

1 Q. Okay. And as you opined in
2 the third bullet that we looked at, the
3 oversupply was created by prescribing for
4 medical uses.

5 A. So let's just go back to the
6 third bullet. What I said in here is
7 that the expansion would not have
8 occurred without the widespread
9 availability of prescription opioids
10 originally dispensed for medical uses.

11 MR. HERMAN: I'm at a place
12 where I could take a break. I'm
13 not quite sure.

14 Why don't we take a break?
15 I think we've been another --

16 MS. DO AMARAL: I don't
17 think we've even gone an hour.

18 MR. HERMAN: Oh, well, my
19 mistake then.

20 THE VIDEOGRAPHER: So I'm --
21 I'm taking just the overall count.

22 The time is 11:31 a.m. Off
23 the record.

24 (Short break.)

1 THE VIDEOGRAPHER: We are
2 back on the record. The time is
3 11:47 a.m.

4 BY MR. HERMAN:

5 Q. Professor Keyes, your
6 opinion is that there's a correlation
7 between rates of prescription opioid
8 supply for medical use and increase in
9 overdose deaths, right?

10 A. Let me see, is that one of
11 the 11 bullet points? Or no? I don't
12 think that's one of the 11 bullet points.
13 I just want to make sure I'm finding it
14 in the report accurately.

15 Q. Well, right now I'm just
16 asking you --

17 A. So I think the
18 epidemiological evidence relates to --
19 you said -- I think there's one part of
20 what you -- let me just read it back, I'm
21 sorry.

22 There's a correlation
23 between rates of prescription opioid
24 supply for medical use.

1 And that's what I don't
2 think the literature differentiates, they
3 look at just the overall distribution of
4 opioids.

5 Q. Well, I direct your
6 attention to the fourth bullet on Page 3.
7 Doesn't it discuss a correlation between
8 overdoses, and I'm quoting here, "with
9 the rates of prescription opioids supply
10 for medical use"?

11 A. I'm sorry, this is the
12 fourth bullet? Oh, prescription opioid
13 overdose increased exponentially. Use
14 increase strongly correlate with rates of
15 prescription opioid supply for medical
16 use.

17 Yes, that is what the report
18 says. I think I will qualify that and
19 say that I -- I think the studies that I
20 cite in that section relate to the
21 prescription opioid supply.

22 Q. Okay.

23 A. So I would just qualify that
24 a little bit.

1 Q. Did -- did you write this as
2 your opinion in your report --

3 A. I wrote it, but -- but now
4 talking it through I think I would --
5 based on the available literature, I
6 would say the supply.

7 Q. Okay. And is the support
8 for this opinion found in Section B.5 of
9 your report?

10 A. B.5.

11 MS. RELKIN: What page is
12 it?

13 MR. HERMAN: Page 20.

14 THE WITNESS: It's Page 21
15 is where the paragraph starts the
16 empirical literature demonstrates
17 an association between the opioid
18 supply and the increase in
19 prescription opioid deaths.

20 BY MR. HERMAN:

21 Q. Okay. And so is your -- the
22 support for your opinion about the
23 correlation between the rate of
24 prescription opioid supply and overdose

1 deaths found in Section B.5 of your
2 report?

3 A. Yes.

4 Q. Okay. Are you relying on
5 any materials not cited in Section B.5 of
6 your report?

7 A. The materials that I cited
8 form the opinion -- form the basis of my
9 opinion.

10 Q. Professor Keyes, did you
11 examine whether there's a correlation
12 between the supply of prescription
13 opioids for medical use in Cuyahoga
14 County and overdose deaths in Cuyahoga
15 County?

16 MS. RELKIN: Objection to
17 form.

18 THE WITNESS: So the data
19 that are drawn on for specifically
20 Paulozzi and Ryan focus on state
21 level data. And so it looks at
22 the correlation between opioid
23 prescribing across states. And
24 opioid dispensing in each state

1 with drug poisoning deaths per
2 100,000.

3 So because these are looking
4 at larger geographic areas,
5 there's no variation within
6 county, right. So within any
7 particular -- you have to look
8 across states and counties in
9 order to observe enough variation
10 to conduct a statistical analysis.

11 So within any particular
12 county, you don't have the
13 geographic variation in
14 prescribing in order to answer the
15 research question.

16 BY MR. HERMAN:

17 Q. Well, I -- I don't think I
18 was asking about variation in
19 prescribing. I was asking, did you
20 examine whether there was a correlation
21 between the supply of prescription
22 opioids for medical use in Cuyahoga
23 County and overdose deaths in Cuyahoga
24 County?

1 MS. RELKIN: Objection to
2 form.

3 THE WITNESS: Right. And so
4 I guess what I'm saying is the way
5 this research question has been
6 approached in the studies that I
7 am looking at here, they rely --
8 you have to have that
9 geographic -- so I guess my
10 question would be within the
11 county where would you find
12 variation in order to assess the
13 correlation?

14 BY MR. HERMAN:

15 Q. Well, so you didn't look at
16 any county-specific data in your analysis
17 about whether the prescription opioid
18 supply corresponds with overdoses?

19 MS. RELKIN: Objection to
20 form.

21 THE WITNESS: The -- what I
22 would say is that the research
23 question itself necessitates an
24 examination across geographic

1 levels.

2 BY MR. HERMAN:

3 Q. And your answer would be the
4 same for data for Summit County?

5 A. Yes.

6 Q. On Page 23 and in Figures 3,
7 4 and 5, so Page 23 to 24, you compare
8 overdose rates in Summit County and
9 Cuyahoga County against national
10 averages, right?

11 A. Yes.

12 Q. Did you consider making a
13 comparison against areas with similar
14 demographics?

15 MS. RELKIN: Objection to
16 form.

17 THE WITNESS: You know, what
18 we wanted to -- what I wanted to
19 convey in these figures is how
20 much higher the overdose -- or how
21 different the overdose death rates
22 are in these two counties compared
23 to the nation. The type of
24 analysis that you're talking about

1 would probably be for a causal --
2 a causal risk factor analysis.
3 And this just descriptively
4 demonstrates the differences in
5 overdose.

6 BY MR. HERMAN:

7 Q. Okay. And you didn't do a
8 causal risk factor analysis?

9 A. So what Figures 3, 4, and 5
10 are is a description --

11 MS. RELKIN: Form.

12 THE WITNESS: -- of overdose
13 death rates across time. That's
14 all -- it's just -- it's the
15 descriptive epidemiology which is
16 a typical surveillance activity
17 that is produced by CDC and
18 multiple other organizations.
19 This is standard for describing a
20 public health problem.

21 BY MR. HERMAN:

22 Q. Did you consider comparing
23 the overdose rate in Summit County
24 against areas of the country with similar

1 supplies of prescription opioids?

2 MS. RELKIN: Objection to
3 form.

4 THE WITNESS: Were -- were
5 the research question to
6 necessitate that type of analysis,
7 that would -- would have been the
8 analysis that I did. However, the
9 research question that I was
10 asking in Figures 3, 4, and 5 was,
11 what is the overdose death rate in
12 these counties and how does it
13 compare to the national average.

14 BY MR. HERMAN:

15 Q. So you didn't consider
16 comparing the counties to areas of the
17 country with similar supplies of
18 prescription opioids?

19 MS. RELKIN: Objection.

20 THE WITNESS: So the
21 research questions that I was
22 asking in Figures 3, 4, and 5 is,
23 what is the drug overdose death
24 rate in these counties and how

1 does it compare to national
2 averages.

3 So consideration of other
4 types of analyses would not have
5 addressed the research question
6 that I asked.

7 BY MR. HERMAN:

8 Q. How did you come up with
9 that research question?

10 MS. RELKIN: Objection to
11 form.

12 THE WITNESS: I was -- how
13 did I come up -- I wanted to
14 document what the surveillance
15 trend showed for the two counties
16 that are under consideration.

17 BY MR. HERMAN:

18 Q. But you decided the best
19 comparison was against the national
20 average?

21 MS. RELKIN: Objection to
22 form.

23 THE WITNESS: So this is a
24 descriptive analysis of what the

1 overdose death rates are in the
2 two counties under consideration,
3 and the national average.

4 If it was a different type
5 of research question, perhaps
6 other comparison groups could also
7 be brought in. But this was a
8 descriptive analysis just to
9 document the overall trends over
10 time.

11 BY MR. HERMAN:

12 Q. On Page 20 of your report
13 around the middle of the first paragraph
14 in Section B.5, you wrote, "Heroin and
15 synthetic opioids began an exponential
16 increase after 2010, and overdose rates
17 due to heroin and synthetic opioids
18 continue to climb." Correct?

19 A. That is what is written.

20 Q. Okay. And that's what the
21 data that you looked at shows?

22 A. So there are a number of
23 different -- that's not what it shows on
24 those figures. But there are other

1 references with regard to specific causes
2 of death.

3 So I just -- are we moving
4 away from the figures?

5 Q. Well, I'm just asking you
6 about the sentence, that the data
7 supported the sentence that you wrote?

8 A. I'm sorry. So is the
9 question what data support this
10 statement?

11 Q. I'm asking you, you believe
12 your statement that "heroin and synthetic
13 opioids began an exponential increase
14 after 2010, and overdose rates due to
15 heroin and synthetic opioids continued to
16 climb" is supported by data that you
17 reviewed?

18 A. Yes.

19 Q. And I'm going to ask you to
20 flip to Page 23. To put together Figures
21 3, 4, and 5, you looked at data from the
22 national vital statistics surveillance
23 system to look at death rates from 2000
24 through 2017?

1 A. Yes.

2 Q. Okay. And you looked at
3 drug rates for all drug-related deaths
4 from 2000 through 2017?

5 A. So it depends on the figure,
6 what outcome that is --

7 Q. Let's start with Figure 3.

8 A. Figure 3 is all drugs.

9 Q. Okay. Death rates for all
10 drug-related deaths?

11 A. Yep.

12 Q. And Figure 4 is death rates
13 for all opioid deaths from 2000 through
14 2017?

15 A. Yes.

16 Q. And Figure 5, which is on
17 Page 25 is overdose death rates for
18 pharmaceutical opioids from --

19 A. So, yeah, that's for deaths
20 that had a T code designation of a
21 pharmaceutical opioid.

22 Q. And under each figure you
23 list the ICD codes that you used to pull
24 data for that figure?

1 A. Yes.

2 Q. So for example, for all drug
3 chart, Figure 5, the ICD codes that you
4 used to pull the data X40 to 44, X60 to
5 65, X85, Y10 to Y14, and contributing
6 causes T36 to 50?

7 MS. RELKIN: Objection to
8 form.

9 THE WITNESS: That -- that
10 is what is written in the
11 footnote.

12 MR. CIACCIO: X64. I think
13 you said 65 by accident.

14 MR. HERMAN: Thank you.

15 MR. CIACCIO: Just for the
16 record.

17 BY MR. HERMAN:

18 Q. In each chart, you used the
19 same ICD codes for underlying causes,
20 right?

21 A. Let me just confirm.

22 Yes.

23 Q. X40 to 44 which are the ICD
24 code -- X40 to 44 are the ICD codes for

1 the different types of accidental
2 poisoning?

3 A. I would need to review
4 the -- I mean, off the top of my head, I
5 don't remember what X42 stands for.

6 Q. Do you know if you included
7 accidental poisonings as an underlying
8 cause?

9 A. I would need to review what
10 the -- what the ICD codes are.

11 Q. Okay.

12 (Document marked for
13 identification as Exhibit
14 Keyes-4.)

15 BY MR. HERMAN:

16 Q. We marked as Exhibit 4 which
17 is a printout of ICD codes.

18 A. Okay. Can I write on this
19 or no?

20 MS. RELKIN: It's an
21 exhibit. If you want to write --

22 BY MR. HERMAN:

23 Q. Okay. So if you look at the
24 first page, the left column you'll see

1 that X40 to 44 is all accidental
2 poisonings, correct?

3 A. Can you just give me a
4 moment to review it? So X40 to 44
5 includes accidental poisoning by an
6 exposure to non-opioid analgesics, et
7 cetera. X41 is accidental poisoning by
8 an exposure to antiepileptic, sedative,
9 hypnotic, et cetera.

10 Q. So they're all accidental
11 poisoning, all categories of accidental
12 poisoning?

13 A. There are other categories
14 of accidental poisoning in the X section
15 that were not used.

16 Q. Yes. But you used X40 to
17 44, which are all categories of
18 accidental poisoning?

19 A. Yes.

20 Q. Okay. And then if you flip
21 to the next page. X60 to 64 are ICD
22 codes for different types of intentional
23 self-poisoning?

24 A. Yes.

1 Q. And those are codes for
2 suicide, right?

3 A. These are intentional
4 self-harm.

5 Q. So suicide or short of
6 suicide, but intentionally afflicted on
7 oneself?

8 A. I would just go with -- I
9 mean, the ICD code is for intentional
10 self-harm.

11 Q. If you flip to the next
12 page, X85 is assault by drugs,
13 medicaments, and biological substances?

14 A. Yes.

15 Q. And if you flip to the next
16 page, Y10 to 14 are ICD codes for
17 different types of poisoning?

18 A. Yes.

19 Q. And the thing that changes
20 in the ICD codes that you're using in
21 Figures 3, 4, and 5, are the codes -- the
22 T code for contributing causes, right?

23 A. Yes.

24 Q. Okay. And so Figure 3 uses

1 T36 to 50, which captures all the drugs
2 that can be contributing causes?

3 MS. RELKIN: Form.

4 (Brief interruption.)

5 THE WITNESS: T36 to 50
6 includes a number of different
7 drugs that can be contributing
8 causes.

9 BY MR. HERMAN:

10 Q. But as represented in the
11 head of your chart, it's all the drugs
12 that can be contributing causes?

13 A. These are the drugs for
14 which there are T codes in T36 to 50.

15 Q. And Figure 4 uses T codes
16 T40.0, T40.1, T40.2 and T40.3 and T40.4,
17 correct?

18 A. Yes.

19 Q. And T40.0 is opium?

20 A. Yes.

21 Q. And T40.1 is heroin?

22 A. Yes.

23 Q. T40.2 is other opioid?

24 A. Yes.

1 Q. T40.3 is methadone?

2 A. Correct.

3 Q. T40.4 is other synthetic
4 narcotics?

5 A. Mm-hmm.

6 Q. And T40.4 includes fentanyl,
7 right?

8 A. There's some variation in
9 how fentanyl has been recorded over time
10 based on who is recording the death
11 certificate. Fentanyl, when it's
12 recorded in the T codes, would be
13 recorded in T40.4, I believe.

14 Q. And that wouldn't
15 differentiate between prescribed fentanyl
16 and illicit fentanyl, would it?

17 A. No.

18 Q. And T40 would also include
19 carfentanil?

20 A. Again, it's a similar issue.
21 I just don't -- I want to make it clear,
22 as I have in this report in numerous
23 places, that there is variation in how
24 the T codes are used across

1 jurisdictions. And there's a number of
2 different sources of that variation.

3 So to the extent that the T
4 codes captured that substance in an
5 overdose or in a poisoning, then it would
6 be captured in T40.4.

7 Q. Okay. And does that mean
8 that if someone overdosed on
9 methamphetamine laced with fentanyl, that
10 it would be coded as T40.4?

11 MS. RELKIN: Objection to
12 form.

13 THE WITNESS: So there is
14 some literature around this and I
15 believe I've cited it in the
16 report. And I can't speak to
17 all -- all overdoses, what would
18 be recorded on the T codes.

19 BY MR. HERMAN:

20 Q. Okay. But it's possible
21 that if an overdose -- if someone
22 overdosed on methamphetamine laced with
23 fentanyl, that it would be coded with
24 T40.4?

1 MS. RELKIN: Objection to
2 form.

3 THE WITNESS: Again, I -- I
4 don't want to speak to all
5 possibilities.

6 BY MR. HERMAN:

7 Q. I'm not asking --

8 A. It depends on who is --

9 Q. Go ahead.

10 I -- I'm asking you is it
11 possible that if someone overdosed on
12 methamphetamine laced with fentanyl that
13 it would be coded with T40.4?

14 MS. RELKIN: Objection to
15 form. Calls for speculation.

16 THE WITNESS: Yeah, I --
17 that's a speculation that I don't
18 want to make --

19 BY MR. HERMAN:

20 Q. You don't know --

21 A. I don't have an opinion on
22 that.

23 Q. You don't know one way or
24 another if it's possible?

1 A. It -- the T codes are used
2 in heterogenous ways across
3 jurisdictions. So what every single
4 jurisdiction does with their T codes and
5 how they code their poisonings is not
6 something that I can speak to in
7 generalities.

8 Q. Okay. But in the
9 hypothetical that I gave you that
10 methamphetamine laced with fentanyl, if
11 someone -- the medical examiner viewed it
12 as -- fentanyl as a contributing cause to
13 that overdose, it's possible they would
14 code it with T40.4?

15 A. Again, I don't want to speak
16 to specific medical examiners. I don't
17 want to speak for them. I don't --
18 medical examiners and coroners use the
19 T codes differently. So I can't speak to
20 the possibility of that.

21 Q. Cocaine-related deaths have
22 been increasing in Cuyahoga County,
23 right?

24 A. I think there is one paper

1 in Cuyahoga County from the medical
2 examiner that looked at specific causes
3 of overdose increases. And to properly
4 answer your question, I'd like to look at
5 that paper. Is that --

6 Q. That's okay. We'll get to
7 that.

8 But you don't -- you don't
9 recall sitting here today whether cocaine
10 overdoses are increasing in Cuyahoga
11 County?

12 MS. RELKIN: Objection.

13 THE WITNESS: Again, I cite
14 it in the report and I would like
15 to look at the paper in order to
16 provide you an accurate answer.

17 BY MR. HERMAN:

18 Q. Okay. We'll come back to
19 it.

20 MS. RELKIN: She has papers
21 right here --

22 MR. HERMAN: That's okay.

23 We'll --

24 MS. RELKIN: -- to answer

1 your question.

2 MR. HERMAN: We'll come back
3 to it.

4 BY MR. HERMAN:

5 Q. If you're looking at
6 Figure 3, which is overdose death rates
7 for all drugs Cuyahoga County-- for all
8 drugs, I'm sorry, Cuyahoga County is
9 close to national average from 2000 to
10 2009, right?

11 A. Can I be honest with you?
12 This is in black and white and I can't
13 see the colors.

14 Q. Oh. I apologize.

15 A. Can I use this one?

16 Q. Yes, please.

17 A. Okay. So now I'm sorry, can
18 you ask it again?

19 Q. Yeah. If you look at
20 Figure 3, which is overdose death rates
21 for all drugs, Cuyahoga County is close
22 to the national average from 2000 to
23 2009, right?

24 A. So I review this in the

1 section, I -- I -- there were a number of
2 years in which it was greater than the
3 national average.

4 Q. Well, that -- that's not my
5 question. From -- and -- from 2000 to
6 2009, Cuyahoga was close to the national
7 average, correct?

8 A. I wouldn't say that that's
9 an accurate statement.

10 Q. You wouldn't say that it's
11 close to national average from 2000 to
12 2009?

13 A. I'll tell you what the exact
14 numbers are.

15 Compared to the national
16 average, pharmaceutical opioid --
17 pharmaceutical opioid deaths were 1.51
18 times higher in Cuyahoga County than in
19 the nation as a whole in 2000. So that's
20 just one example.

21 Q. Well, I -- I appreciate that
22 example.

23 A. So it -- I wouldn't -- I --
24 I wouldn't say it's similar.

1 Q. I'm directing your attention
2 to Figure 3. And --

3 A. Oh I'm sorry, that was
4 Figure 4.

5 MS. RELKIN: And let -- let
6 me just note my objection that you
7 gave the witness the binder saying
8 it's easier to use, and the binder
9 is black and white. The actual
10 exhibit is color. So let's --

11 MR. HERMAN: It certainly
12 was not my intention. Someone
13 printed it in black and white. I
14 was trying to be helpful to the
15 witness. And I'm happy you were
16 able to hand her a color copy. We
17 certainly would have provided her
18 one.

19 MS. RELKIN: From now on
20 don't use the binder. Use the
21 exhibit.

22 MR. HERMAN: Okay.

23 MS. RELKIN: That should be
24 that one going forward.

1 BY MR. HERMAN:

2 Q. All right. So looking at
3 Figure 3, you wouldn't say that from
4 2009 -- from 2000 to 2009, that Cuyahoga
5 County is close to the national average
6 for overdose rates for all drugs?

7 A. No. I think it's higher in
8 2000, 2001, 2002. Slightly lower in
9 2003. Slightly higher in 2004. Quite a
10 bit higher in 2006. I would say it's
11 similar in 2007. It's higher in 2008.

12 Q. You -- you'd agree that some
13 years it's above, some years it's below?

14 MS. RELKIN: Objection to
15 form. Overbroad.

16 THE WITNESS: I would say
17 that it -- there are one, two,
18 three, four, five, six, seven --
19 of the years that you asked me to
20 review, there are seven years in
21 which it's above.

22 There is one year in which
23 it's below, and one in which it's
24 similar.

1 BY MR. HERMAN:

2 Q. Okay. You -- you only see
3 one year where it's below? It's not
4 below in 2003 --

5 A. 2003 --

6 Q. -- 2009 as well?

7 A. Oh, I'm -- would you -- you
8 were asking me to be inclusive of 2009?

9 Q. Yes, through 2009.

10 A. So if I -- I -- if I'm
11 inclusive of 2009, then it's two.

12 Q. Okay. And Cuyahoga begins
13 to be steadily above the national average
14 starting in 2010, right?

15 A. I think they were steadily
16 above the national average prior to 2009
17 as well.

18 Q. But there's a significant --
19 the increase -- the trend up on a
20 continuous path begins in 2010?

21 A. So, I mean, the most
22 accurate statement that I can make is
23 that after 2010 there is no year in which
24 it is below the national average.

1 Q. And that's due to cocaine
2 and heroin overdoses, right?

3 A. So again, I can --

4 MS. RELKIN: Objection to
5 form.

6 THE WITNESS: There is a
7 report from the medical examiner
8 in Cuyahoga County that we could
9 pull out to examine -- look at
10 this issue.

11 What I've stated in the
12 report, I think more germane to
13 your question, is that we know
14 from the available epidemiological
15 evidence that 80 percent -- up --
16 more -- upwards of 80 percent, and
17 perhaps more than 80 percent of
18 people who use heroin, especially
19 in recent years, began their
20 opioid-using careers with
21 prescription opioids.

22 I also have data cited here
23 that many heroin users also use
24 prescription opioids while they

1 are using heroin.

2 BY MR. HERMAN:

3 Q. Well, let's go to Figure 5.

4 MS. RELKIN: So you don't
5 want her to pull the literature
6 she was referring to, the data?

7 MR. HERMAN: I'm fine right
8 now.

9 BY MR. HERMAN:

10 Q. So Figure 5 has the T codes
11 for heroin and opium removed, correct?

12 A. I'm sorry, I'm just going to
13 compare it to the ICD-10. So there's a
14 pen mark on here. And I can't -- this is
15 T40.4. So this is T40.2, 3, and 4, which
16 includes other opioids, methadone, and
17 other synthetic narcotics.

18 Q. And this chart no longer
19 includes heroin and opium, correct?

20 A. It no longer includes T
21 codes 40.0 and 40.1, correct.

22 Q. Okay. And with the removal
23 of the T code for heroin, does Cuyahoga
24 stay closer to the national average at or

1 below the national average until it
2 undergoes a significant spike in 2015?

3 MS. RELKIN: Objection to
4 form.

5 THE WITNESS: So in 2000 --
6 one, two, three, four -- and
7 through 2009 -- so inclusive of
8 2009, prior to 2009 there are four
9 years in which Cuyahoga is above
10 the national average in terms of
11 overdose.

12 And then one, two,
13 three years in which I would say
14 that it is roughly approximate to
15 the national average. No, I'm
16 sorry, four years I would say it's
17 roughly above the national
18 average, which by the way is
19 increasing across that time. I
20 mean, it should be noted since
21 2013 we had we've had to change
22 the Y axis for these overdose
23 deaths.

24 BY MR. HERMAN:

1 Q. Let me -- me ask you the
2 question a little differently.

3 Comparing Figure 4 to Figure
4 5, does that comparison suggest to you
5 that the increase in overdose deaths
6 starting in 2010 was due to heroin?

7 MS. RELKIN: Objection to
8 form.

9 THE WITNESS: Let me just
10 read the question again.

11 Comparing Figure 4 to Figure
12 5, does that comparison suggest to
13 you that the increase in overdose
14 deaths starting in 2010 was due to
15 heroin?

16 I haven't done an analysis
17 specifically of that question. So
18 I wouldn't speculate.

19 BY MR. HERMAN:

20 Q. You can't figure that out by
21 comparing Figure 4 to Figure 5 and the
22 differences --

23 MS. RELKIN: Objection.

24 BY MR. HERMAN:

1 Q. -- in the T codes?

2 MS. RELKIN: Objection to
3 form.

4 THE WITNESS: No I would
5 need to do a statistical analysis
6 of that.

7 BY MR. HERMAN:

8 Q. Okay. And do you believe
9 that the spike that occurs in Cuyahoga
10 County in 2015 is due to fentanyl?

11 MS. RELKIN: Objection to
12 form.

13 THE WITNESS: So, again, we
14 have the data from Cuyahoga County
15 medical examiner in this box that
16 I could produce, where they have
17 actually answered that question.
18 I can --

19 BY MR. HERMAN:

20 Q. We're going to look at that
21 in a second. But you can't figure that
22 out from these charts?

23 MS. RELKIN: Objection to
24 form.

1 THE WITNESS: I would rely
2 on the medical examiner from that
3 county who's evaluated that very
4 question rather than make
5 assumptions about what's in the
6 figures.

7 BY MR. HERMAN:

8 Q. And does a comparison from
9 Figure 4 to Figure 5 suggest to you that
10 fentanyl is a cause of the increase in
11 overdose deaths that begins in 2013 for
12 Summit County?

13 MS. RELKIN: Objection to
14 form.

15 THE WITNESS: I think I've
16 answered the question that there's
17 a number of T codes that are
18 included. And the data from
19 Cuyahoga County on carfentanil
20 deaths is in the box. And so I
21 can -- and maybe you have it as an
22 exhibit that we can look at.

23 BY MR. HERMAN:

24 Q. That's a good point. You

1 think that it might be due to carfentanil
2 instead of fentanyl --

3 A. I believe --

4 Q. -- in Summit County?

5 A. -- the data is in the box.

6 We can look at it.

7 Q. We'll do that.

8 (Document marked for
9 identification as Exhibit
10 Keyes-5.)

11 BY MR. HERMAN:

12 Q. I'm handing you what's been
13 marked as Exhibit 5. I believe this
14 is --

15 A. Yeah.

16 Q. -- some of the data you've
17 wanted to look at?

18 A. Yes.

19 Q. Okay. So I direct your
20 attention to Page 43.

21 A. Okay.

22 Q. Okay. And so if we look at
23 Page 43, the blue line is all opioids not
24 including fentanyl, correct?

1 A. Yes.

2 Q. And that's a category that
3 would include prescription opioids?

4 A. I need to go to their
5 methodology where they cite what ICD
6 codes they used for that designation.
7 Let's see if they have it in their
8 methods.

9 So I don't see here where
10 they've listed T codes for that specific
11 category -- I mean, I'm sorry, ICD codes
12 for that specific category, all opioids
13 not including fentanyl. I can't speak to
14 what ICD codes were included.

15 Q. Okay. Is there --

16 A. It says -- the paper writes
17 "all opioids, not including fentanyl."

18 Q. And is there another
19 category captured on this chart that you
20 believe is prescription opioids?

21 A. Again, without the
22 methodology that was used, I don't want
23 to speak to -- I can tell you what the
24 paper says. I just --

1 Q. And I should say, this is
2 data for overdoses in Cuyahoga County
3 from 2006 to 2016.

4 A. 2016 has an asterisk by it.
5 So 2016 cases are projected from third
6 quarter data. So I wouldn't -- I would
7 just make that qualification that it's
8 through 2016 third quarter with respect
9 to the data.

10 Q. And -- but this is the data
11 that you used in your report for the
12 comparison of the rise in total overdose
13 mortality in Cuyahoga County, has
14 increased from 250 in 2006 to 608 in
15 2016?

16 A. Yes. This is the paper that
17 I cited.

18 Q. And if we look at the blue
19 line -- I'm sorry.

20 If we look at the green
21 line, that is overdoses from cocaine?

22 A. What the authors write is
23 that these are the cocaine overdoses.

24 Q. And the black line is

1 heroin?

2 A. Again, that's what the
3 authors write.

4 Q. And the red line is
5 fentanyl?

6 A. That is what the authors
7 write.

8 Q. Okay. Does this confirm for
9 you that the increase in overdose deaths
10 shown on Figure 5 of your report in 2015
11 is due to fentanyl?

12 MS. RELKIN: Objection to
13 form. Overbroad.

14 THE WITNESS: So in Figure
15 5, I document that, based on the
16 national vital statistics data
17 that the overdose rate in Cuyahoga
18 is about -- is at about 35 per
19 100,000. And that's 2015.

20 And here, based on the
21 data -- again, I would need to do
22 a statistical analysis to actually
23 compare what causes of death
24 contributed. But based on my

1 reading of this in 2015, compared
2 to 2013, there are increases in
3 what they describe as
4 fentanyl-related deaths, yes.

5 BY MR. HERMAN:

6 Q. And assuming that the blue
7 line is a category that includes
8 prescription opioids, the number of
9 overdose deaths attributed on the
10 Cuyahoga data to prescription opioids has
11 remained relatively flat from 2006 to
12 2016?

13 MS. RELKIN: Objection.

14 THE WITNESS: Well, I think
15 that that's -- I think it should
16 be qualified in that it's not
17 clear from this whether -- whether
18 there was prescription opioids in
19 the toxicology of individuals who
20 died from fentanyl overdoses.

21 So we don't know based on
22 this what the entire lifetime
23 history of drug use of the
24 individuals who overdosed was.

1 So these increases in
2 fentanyl deaths could have come
3 from prescription opioids or other
4 sources of drugs.

5 BY MR. HERMAN:

6 Q. The cause of --

7 A. You're saying the all
8 opioids line has gone down. And you said
9 that that includes prescription opioids.

10 And I'm saying that I don't
11 think that the data show that.

12 Q. Well, I'm asking you, I mean
13 in 2006, the overdose deaths in Cuyahoga
14 County that the medical examiner said
15 were due to all opioids not including
16 fentanyl was 81, correct?

17 A. Let me -- let me just read
18 the question back.

19 "In 2006 the overdose deaths
20 in Cuyahoga County that the medical
21 examiner said were due to all opioids not
22 including fentanyl was 81." Yes, that's
23 correct.

24 Q. And in 2015, the number of

1 deaths that the county medical examiner
2 said were due to all opioids not
3 including fentanyl were 80?

4 A. That is what is written in
5 the paper.

6 Q. And in 2016, the number that
7 the county medical examiner attributed to
8 all opioids not including fentanyl for
9 overdose deaths was 89?

10 MS. RELKIN: Objection to
11 form.

12 THE WITNESS: Again, that is
13 projected from third quarter data,
14 so I just want to make sure that
15 asterisk is noted. You don't -- I
16 don't think this paper provides a
17 final count.

18 And again, there is -- we
19 don't know the ICD codes that were
20 used in this analysis. Based on
21 what the authors of this paper
22 wrote, they wrote that all
23 opioids, not including fentanyl, a
24 projected number for 2016, was 89.

1 But again, that doesn't
2 assess the lifetime history and
3 toxicology of the decedent at the
4 time of the death.

5 BY MR. HERMAN:

6 Q. You don't know that, right?

7 A. Don't know?

8 Q. Your point is that you don't
9 know all the toxicology.

10 A. I don't understand the
11 question.

12 Q. Well, you're saying that
13 doesn't assess the lifetime history and
14 toxicology of the decedent at the time of
15 death.

16 And your point is that you
17 don't have that information, you don't
18 know that information?

19 MS. RELKIN: Objection to
20 form.

21 THE WITNESS: What I am
22 saying is that if the idea is that
23 prescription opioid death didn't
24 increase across this time, I don't

1 think these data speak to that
2 issue, which I think is what the
3 question is.

4 BY MR. HERMAN:

5 Q. Okay. You would agree with
6 me that from 2015 to 2016, fentanyl
7 deaths went from 92 to 34, or to 394?

8 A. In 2015 the number of deaths
9 that were characterized by the medical
10 examiner as due to fentanyl -- I just --
11 hold on. I just want to read the methods
12 again. I'm sorry, I just want to make
13 sure I get this...

14 I want to -- okay. So just
15 so we can have a consensus about the
16 methods.

17 So this analysis involved
18 deaths that were unnatural, suspicious,
19 or involved sudden unexpected death of a
20 person in apparent good health.

21 Autopsy doesn't seem to have
22 been done on all cases. Is that correct?
23 Suspected drug-related deaths with little
24 or no medical intervention are

1 transported to the mortuary for full
2 autopsy. Death after hospitalization
3 with adequate evaluation may be viewed
4 with no autopsy.

5 And so then they did
6 toxicological testing on admission
7 samples.

8 I just want to -- so this
9 doesn't involve T codes. So I want to --
10 I'm not -- this is on the toxicological
11 testing. I want to make sure that that
12 is accurate.

13 Q. Professor Keyes --

14 A. Back to your question about
15 the fentanyl.

16 So it looks like of those
17 toxicological tests that were performed
18 on those who died who were -- had deaths
19 that were unnatural, suspicious or
20 involved a sudden unexpected death in
21 apparent good health, the medical
22 examiner identified fentanyl in 92 cases
23 in 2015 and 394 in -- projected in 2016.

24 Q. And, Professor Keyes, you

1 use these statistics for a comparison of
2 total overdose mortality in Cuyahoga
3 County from 2006 to 2016, correct?

4 A. 250 in 2006 and 608 in 2016,
5 that's correct.

6 I also talk in that section
7 about the specific increase from 2015 to
8 2016, again noting that, you know, the
9 majority of the increase in total
10 overdose deaths is due to that increase
11 in fentanyl and heroin, which would be in
12 about 80 percent of cases, perhaps more,
13 secondary to the use of prescription
14 opioids.

15 Q. Did you look at any data
16 specific to Cuyahoga County to confirm
17 that 80 percent --

18 A. I -- to that -- I -- that is
19 an issue that is -- is -- I thought about
20 a lot.

21 And the data sources that
22 are used to describe the proportion of
23 individuals, especially in recent years
24 that use heroin come from a wide variety

1 of heterogenous populations and converge
2 on similar estimates. If it were a small
3 number of studies in a select group of
4 people that probably weren't similar to
5 a -- you know, heterogenous group of
6 heroin users, I would be more qualified.
7 But given the number of studies, I think
8 in -- I think I reviewed 16, but I can
9 check -- and given their geographic
10 sample selection and other types of
11 characteristics, I think it is the -- the
12 level with which the data are consistent
13 would lend itself to a scientific
14 decision that there is good evidence of
15 generalizability.

16 Q. Did you look at data
17 specific to Summit County?

18 A. Data on?

19 MS. RELKIN: Objection to
20 form.

21 THE WITNESS: The heroin
22 users?

23 BY MR. HERMAN:

24 Q. Data on the 80 percent

1 figure that you're using, to support the
2 80 percent figure that you're using?

3 A. Again, I just explained the
4 methodology that I used. I -- I -- in
5 terms of the epidemiological evidence
6 that I reviewed, I have not found a study
7 that assessed heroin users specific to
8 those areas. That being said, there's a
9 wide variety of studies in many different
10 areas, in many different patient and
11 street user and treatment populations and
12 general populations, and the results are
13 consistent.

14 Q. Okay. And the many studies
15 you're speaking to are the ones you
16 discuss in Section B.7 of your report?

17 A. Let's just be specific.
18 Yes. 16 studies.

19 Q. Okay. And when -- earlier
20 you said you didn't look at data for
21 those areas, those areas were Summit and
22 Cuyahoga County specifically?

23 A. I'm sorry, can you be
24 specific?

1 Q. I believe you said, "I
2 didn't look at data specific to those
3 areas." And I'm just asking, when you
4 use the term "those areas," were you
5 referring that you didn't look at data
6 about the 80 percent figure specifically
7 for Cuyahoga and Summit County?

8 MS. RELKIN: Objection to
9 form.

10 THE WITNESS: So to my
11 knowledge, there is no existing
12 epidemiological study in the
13 evidence base that specifically
14 interviews heroin users in those
15 specific counties.

16 However, of the studies that
17 I reviewed, there was a broad
18 range of populations. So I --
19 based on my scientific assessment,
20 there would be generalizability to
21 other areas.

22 MR. HERMAN: Do people want
23 to break for lunch? I can go for
24 a little longer --

1 MS. DO AMARAL: Why don't
2 you go for a while.

3 MS. RELKIN: Go for a little
4 longer.

5 MS. DO AMARAL: We've only
6 been going 45 minutes.

7 MR. HERMAN: Sure.

8 BY MR. HERMAN:

9 Q. Professor Keyes, did you
10 conduct a search for articles related to
11 a relationship between the supply of
12 opioids and overdoses?

13 THE WITNESS: Did you
14 conduct a search?

15 MS. RELKIN: Objection to
16 form.

17 BY MR. HERMAN:

18 Q. Strike that. Let me
19 rephrase the question.

20 Did you conduct a search for
21 articles related to a relationship
22 between the supply of prescription
23 opioids and overdoses?

24 A. Okay. I'm sorry.

1 "Did you conduct a search
2 for articles related to a relationship
3 between the supply of prescription
4 opioids and overdoses?"

5 MS. RELKIN: Form.

6 THE WITNESS: Those articles
7 are cited on page --

8 BY MR. HERMAN:

9 Q. The -- the articles that you
10 located are discussed in Section B.5 on
11 that topic.

12 A. Is it B.5?

13 I believe it starts on
14 Page 21. "The empirical literature
15 demonstrates an association between the
16 opioid supply and increase in
17 prescription opioid deaths."

18 Those were the articles that
19 form the basis of my opinion.

20 Q. And the articles discussed
21 in Section B.5 looked at a correlation
22 between prescription opioids and over
23 death -- overdose deaths, right?

24 MS. RELKIN: Objection to

1 form.

2 THE WITNESS: Can we go
3 through each study?

4 BY MR. HERMAN:

5 Q. You don't recall whether the
6 articles --

7 A. So there's a number of
8 different studies. Some are -- some are
9 quasi-experimental, which I think are a
10 different level of evidence. So
11 there's -- there's a broad range of
12 studies with a number of different study
13 designs in heterogenous populations.

14 Q. Okay. Can you point me to
15 an article that goes beyond showing a
16 correlation between prescription opioids
17 and overdose deaths?

18 MS. RELKIN: Objection to
19 form.

20 THE WITNESS: Can you define
21 what you mean by "correlation."
22 Because --

23 BY MR. HERMAN:

24 Q. Well, I'm using --

1 A. -- randomized controlled
2 trials also show correlations.

3 Q. I'm using the terminology
4 that you used, which was that there's a
5 correlation with rates of prescription
6 opioids supplied for medical use with
7 overdose deaths.

8 MS. DO AMARAL: Counsel,
9 what page, please?

10 MR. HERMAN: Page 3.

11 THE WITNESS: So are you
12 referring to "and these increases
13 strongly correlate with rates of
14 prescription opioid supply"? Is
15 that --

16 BY MR. HERMAN:

17 Q. Yeah, I mean --

18 A. -- the quote you mean?

19 Q. -- you've described it as a
20 correlation. Are you --

21 A. I mean, all associations are
22 correlations. So -- but is that
23 specifically what you're referring to,
24 "Prescription opioid overdose increased

1 exponentially in the United States in the
2 past 20 years, and these increases
3 strongly correlate with rates of
4 prescription opioid supply for medical
5 use, both in terms of geographic
6 variation and supply as well as
7 year-to-year variation"? Is that -- I
8 just want to make sure I'm on the right
9 bullet point.

10 Q. Yes. That's where I got the
11 prescription.

12 A. Right. So I said in both
13 observational and quasi-experimental
14 studies. So the quasi-experimental
15 study -- I can go through the
16 observational evidence as well. But the
17 quasi-experimental study in particular
18 was Powell 2015.

19 What is useful about that
20 particular study is that they used the
21 changes in the Medicare prescription drug
22 benefit program in 2006. And what makes
23 that quasi-experimental is that there's
24 nothing about the characteristics of the

1 users that would have changed Medicare.
2 That that was an exogenous source of
3 variation. And so oftentimes in
4 epidemiology, we try to find these
5 sources of variation that are exogenous
6 in order to build the evidence base.

7 So what they did is -- and
8 that study from 1999 through 2016, they
9 looked at the Medicare expansion and how
10 that affected the opioid supply.

11 Q. I'm going to let you
12 continue. But I don't think you're
13 answering my question anymore.

14 A. Okay. So what is --

15 MS. RELKIN: You
16 interrupt -- you did interrupt her
17 answer. So she was answering your
18 question.

19 THE WITNESS: Your question
20 was whether there was a
21 correlation between the opioid
22 supply and --

23 BY MR. HERMAN:

24 Q. Whether the articles that

1 you used show a correlation between the
2 opioid supply --

3 A. So then I'm answering the
4 question.

5 Q. Why don't we just -- I'll
6 hand you that study, which I marked as
7 Exhibit 6.

8 MS. RELKIN: You didn't
9 complete --

10 THE WITNESS: Do you want me
11 to --

12 MS. RELKIN: Can she please
13 complete her answer?

14 (Document marked for
15 identification as Exhibit
16 Keyes-6.)

17 BY MR. HERMAN:

18 Q. You can finish your answer.

19 A. Okay. I would, one, take a
20 step back and describe what I mean by
21 correlation, which is an association
22 between an exposure and an outcome in a
23 study.

24 Powell 2015 used a

1 quasi-experimental design using the
2 source of exogenous variation, which was
3 the Medicare prescription drug benefit
4 Part D.

5 The patient -- the
6 population that was examined for the
7 study was individuals over 65 years old.
8 The increase in the opioid supply was
9 documented based on ARCOS data, which we
10 can get into if you'd like to.

11 And they looked at drug
12 overdose deaths. So for both
13 prescription deaths and for treatment
14 admissions, there was evidence that the
15 increase in the opioid supply was
16 associated with deaths and treatment
17 admissions.

18 Q. And let's just -- if you
19 look at Page five of that study. They
20 found a strong positive relationship
21 between elderly share and the growth in
22 prescription opioids distributed at the
23 state level?

24 A. So if you want me to speak

1 to that particular sentence, I just need
2 to orient myself to the study. Can I
3 take a minute and -- thank you.

4 Q. Do you --

5 A. I'm not allowed to underline
6 on this, right?

7 MS. RELKIN: Do you want to
8 work off mine?

9 THE WITNESS: Do you mind if
10 I work --

11 BY MR. HERMAN:

12 Q. Professor Keyes, I mean, you
13 just gave me a long recitation about what
14 the study was about.

15 Do you -- do you not recall?

16 A. You're asking about one
17 sentence in the introduction. And so --

18 MS. RELKIN: You can go
19 through mine.

20 BY MR. HERMAN:

21 Q. I'm asking you --

22 A. You're asking about a
23 sentence in the introduction that says
24 that there's a strong positive

1 relationship between elderly share and
2 the growth of prescription of opioids
3 distributed at the state level?

4 Q. Does that mean more people
5 over 65 -- that the more people over 65
6 in the state, the higher the amount of
7 prescription opioids in that state?

8 A. I'm going to have to take a
9 step back and review the previous
10 paragraph.

11 So what this paper shows --
12 I mean, the previous paragraph suggests
13 that they provide the first causal
14 evidence that increasing prescription
15 opioid access escalates substance abuse
16 and mortality for populations not
17 directly gaining medical access to these
18 drugs.

19 That particular sentence
20 does refer to the relationship between
21 elderly share and growth in prescription
22 opioids and I believe -- and we can
23 confirm that that was part of the
24 modeling that was done.

1 So the conclusions from the
2 paper are not dependent on that
3 relationship.

4 Q. But the more -- doesn't that
5 study -- didn't the study find that the
6 more people over 65 in the state, the
7 higher the amount of prescription opioids
8 in the state?

9 A. I don't believe that's what
10 the study -- the specific comparisons
11 that were done.

12 Q. That's not what it means
13 when they say, "We find a strong
14 causative relationship between elderly
15 share and the growth in prescription
16 opioids distributed at the state level"?

17 A. So maybe we can go through
18 each table.

19 Q. Well, I prefer not to do
20 that. Do you --

21 A. I don't --

22 MS. RELKIN: Object to form.

23 THE WITNESS: But that's

24 the -- that what the study -- the

1 focus -- the focus of the study is
2 the causal relationship between
3 prescription opioid access and
4 substance abuse and mortality. So
5 part of evaluating that is
6 evaluating things like the
7 positive relationship between
8 elderly share and growth in
9 prescription opioids.

10 But that's not the
11 conclusion of the paper. That's
12 not the --

13 BY MR. HERMAN:

14 Q. What the study was
15 theorizing, right, is that older people
16 were prescribed opiates for medical
17 reasons pursuant to Part D of Medicare,
18 and that created the opportunity for, as
19 they termed it, spillover for nonmedical
20 use, right?

21 A. I'm just going to read your
22 question.

23 MS. RELKIN: Objection to
24 form.

1 THE WITNESS: What the study
2 was theorizing is that older
3 people were prescribed opioids for
4 medical reasons pursuant to Part D
5 of Medicare and that created the
6 opportunity for, as they termed
7 it, spillover into nonmedical use.

8 I don't believe that's what
9 these comparisons are.

10 They're exploiting the
11 changes in Medicare Part D by
12 state to look at the relationship
13 between opioid supply and
14 treatment admissions and overdose.

15 BY MR. HERMAN:

16 Q. And the -- what they were
17 looking at is Medicare Part D which is
18 for people over the age of 65, right?

19 A. Yeah, the population that
20 they were looking at was people over 65.

21 Q. And the more people over 65
22 in the state, the higher the opioid
23 supply for medical use?

24 A. Again, I don't think that

1 that was the mean comparison and
2 statistical model that was conducted by
3 the authors. I mean, in Formula 1, they
4 are looking at the opioid-related
5 distribution, abuse or mortality for
6 states across time. And there is a
7 number of different vector of time
8 varying covariates, including the time
9 varying measure of elderly share.

10 Q. On Page 6, did they state,
11 "Extrapolating our results to the full
12 time series are evidence that suggest
13 that 73 percent of dramatic growth in
14 opioid-related overdose deaths can be
15 attributed to spillovers resulting from
16 increased medical access"?

17 A. That is one sentence in --
18 that builds their overall argument. But
19 again I would point to the actual
20 comparisons that were done in the results
21 section.

22 Q. Their overall argument that
23 increased access to opioids for people
24 over the age of 65 through medical --

1 through Medicare Part D, provided the
2 opportunity for diversion from pills
3 prescribed for medical reasons?

4 A. So they -- I'm just going to
5 quote the authors in terms of how they
6 describe the results to make sure that --
7 so the authors describe the results as
8 they interpret their estimates as -- this
9 is on Page 25. "We interpret our
10 estimates as spillovers resulting from
11 the implementation of Part D and more
12 generally from increased medical access
13 to opioids. We find that overdoses
14 increase among a population that does not
15 directly gain medical access to these
16 drugs."

17 So that's their
18 interpretation.

19 Q. Right. And the people who
20 don't directly gain medical access are
21 the spillover effect, right?

22 A. I just want to be really
23 clear about how they are defining
24 spillover.

1 Do you know the first time
2 in -- in the article that that term is
3 used?

4 Q. I believe it's the sentence
5 that I read to you on Page 6, but --
6 and -- "extrapolating our results to the
7 full time series, our evidence suggests
8 that 73 percent of the dramatic growth in
9 opioid-related overdose deaths can be
10 attributed to spillover resulting from
11 increased medical access."

12 A. Yeah, I think that is the
13 first time it is used. They don't
14 specifically define spillover. So I
15 can't speak to what their definition was
16 in this study.

17 Q. You can't tell from that
18 quote what they mean by spillover?

19 A. No.

20 (Document marked for
21 identification as Exhibit
22 Keyes-7.)

23 BY MR. HERMAN:

24 Q. I'll hand you what I've

1 marked as Exhibit 7.

2 This is another article,
3 "The Epidemiological Association Between
4 Opioid Prescribing and Nonmedical Use and
5 Emergency Department Visits," that you
6 cited in Section B.5 of your report.

7 A. Yes. That's what --
8 Page 21, the last paragraph.

9 Q. And this study looked at
10 correlation, correct?

11 A. So again I'm just going to
12 ask what you mean by correlation. All
13 statistical models are estimating the
14 relationship between an independent
15 variable and an outcome variable.

16 Q. Okay. So --

17 A. So they are assessing the
18 relationship between an independent
19 variable and an outcome variable just
20 like any study.

21 Q. Okay. And they were looking
22 at correlation between certain types of
23 prescription opioids and nonmedical use?

24 A. Okay. Hold on a second. So

1 this study utilizes four national
2 datasets and looks at the correlation
3 between prescribing self-reported
4 nonmedical use, drug-induced and
5 drug-related E.D. visits for hydrocodone,
6 oxycodone and morphine.

7 So I wouldn't agree that
8 they are only looking at the correlation
9 between certain types of prescription
10 opioids and nonmedical use. They are
11 also looking at drug-induced and
12 drug-related E.D. visits.

13 Q. That was going to be my next
14 question. So...

15 A. Okay.

16 Q. Thank you though.
17 Appreciate it.

18 If you turn to the
19 limitations on Page 8. And the sentence:
20 "By its very nature, secondary data
21 analysis and the tests of association
22 utilized are not conducive to
23 establishing cause-and-effect
24 relationships."

1 Do you see -- do you see
2 where I just read?

3 A. Yes. Again, I -- I put
4 together a body of evidence here that I
5 think shows the relationship in a number
6 of different studies and a number of
7 different datasets. One study is really
8 never enough to conclude that there's a
9 causal relationship. But as the evidence
10 builds from different types of study
11 designs, I think the weight of the
12 scientific evidence becomes more clear.

13 So I just want to point that
14 out. In terms of this particular study,
15 they were looking at, you know,
16 correlations across these different
17 datasets. But it's presented in the
18 report as a body of evidence, a broader
19 body of evidence.

20 Q. But at least with respect to
21 this report, they said that the analysis
22 and the tests of association utilized are
23 not conducive to establishing
24 cause-and-effect relationships, right?

1 MS. RELKIN: Objection to
2 form.

3 THE WITNESS: In this
4 particular study, the methodology
5 that was used examines
6 correlations between prescribing
7 and these different outcomes. If
8 this were the only study that were
9 ever done on the opioid supply, I
10 think there would be a limited
11 case for a causal relationship.

12 However, there is a body of
13 evidence that I think builds the
14 case more concretely.

15 BY MR. HERMAN:

16 Q. And in the conclusion
17 section they also said, "To determine if
18 the association observed in this study
19 between increased supply as a result of
20 prescribing and increased problems
21 manifested by nonmedical use and
22 drug-induced and drug-related E.D. visits
23 represent an actual cause-and-effect
24 relationship, different study methodology

1 is warranted"?

2 MS. RELKIN: Are you asking
3 her does it say that?

4 THE WITNESS: What was the
5 question?

6 BY MR. HERMAN:

7 Q. Yeah. I asked, did -- in
8 the conclusion, did they say --

9 A. So again, I think that this
10 study is presented in a body of evidence.
11 So this particular study looks at
12 correlations. But there are a number of
13 other studies that again look at the same
14 relationship in different study designs
15 and different populations using different
16 methodology. And so I think while this
17 particular study looks at one set of
18 correlations, when presented overall with
19 the other weight of the evidence, I think
20 the evidence is more strong that there is
21 a causal relationship between the supply
22 of opioids and opioid-related harm.

23 Q. Are DAWN recorded E.D.
24 visits limited to cases of overdose?

1 A. Are DAWN recorded E.D.
2 visits related -- so the Drug Abuse
3 Warning Network is medical record and
4 toxicology screening data. So there's
5 other data that are also included in
6 DAWN.

7 Q. Beyond just overdoses?

8 A. Based on my knowledge, yes.

9 Q. A drug-related emergency
10 department visit means that someone
11 documented the prescription opioid as a
12 contributing factor to the emergency
13 department visit, right?

14 A. They don't say here in their
15 methodology -- oh, here we go hold on a
16 second. The DAWN dataset.

17 So yes, they included in
18 this particular study the number of E.D.
19 drug episodes per year, which mention a
20 hydrocodone, oxycodone, or
21 morphine-containing product.

22 Q. Are there lots of reasons
23 that a prescription opioid might be
24 mentioned with respect to an emergency

1 department visit?

2 MS. RELKIN: Objection to
3 form.

4 THE WITNESS: I can't speak
5 to all emergency departments.

6 BY MR. HERMAN:

7 Q. Well, do you know one way or
8 another if there are lots of reasons that
9 a prescription opioid might be documented
10 with regard to emergency department
11 visit?

12 MS. RELKIN: Objection to
13 form.

14 THE WITNESS: I -- I --
15 again, I don't know -- the
16 methodology for this particular
17 study doesn't cite, it is any
18 mention of these medications. So
19 the reasons that any one
20 particular hospital might list
21 them are not within the purview of
22 the scope of what I reviewed in
23 the epidemiological evidence.

24 MR. HERMAN: Shall we break

1 for lunch?

2 MS. DO AMARAL: Sounds good.

3 THE VIDEOGRAPHER: Okay.

4 Remove your microphones, please.

5 The time is 12:53 p.m. Off the

6 record.

7 - - -

8 (Lunch break.)

9 - - -

10 A F T E R N O O N S E S S I O N

11 - - -

12 THE VIDEOGRAPHER: All

13 right. We are back on the record.

14 The time is 1:32 p.m.

15 - - -

16 EXAMINATION (Cont'd.)

17 - - -

18 BY MR. HERMAN:

19 Q. Professor Keyes, would you

20 be able to provide me a list of the

21 search terms that you used in PubMed?

22 A. So I think we've been over

23 this. I think the methodology that I

24 used is stated in this report. I used a

1 variety of different searches for each of
2 the different topics that are included in
3 this -- in the expert report.

4 Q. I understand the methodology
5 that's listed there, but you would agree
6 that it doesn't list the search terms,
7 right?

8 A. I would agree that the
9 particular search terms for every single
10 section are not listed in the report.

11 Q. And so my question is --
12 well, are any of the search terms listed
13 in the report?

14 A. Again, I have -- I think
15 I've been clear about the methodology
16 that I used, which is well accepted in
17 the peer-reviewed literature. It was
18 not -- it did not include a list of
19 search terms. I've done many literature
20 reviews that are published in the
21 literature. Some of them have included
22 search terms, some of them have not.
23 This one in particular did not because of
24 the scope of what I was asked to review

1 was heterogenous and wasn't warranted for
2 the topic.

3 Q. Okay. So I understand that
4 you covered heterogenous topics. But
5 would you be able to provide me with a
6 list of the search terms that you used?

7 A. I think what I've described
8 in here is the methodology that I used,
9 which was a critical review of the
10 literature. I did not include in here
11 every single search term that I reviewed
12 in terms of -- in every single section.

13 Q. There are no search terms in
14 any sections, right?

15 A. I didn't include search
16 terms. Again, that is a common practice
17 in the epidemiological literature for
18 literature reviews. Some include
19 specific search terms; some don't. This
20 is standard practice in the field.
21 There's nothing that is against the
22 scientific practice that I participate in
23 in this review.

24 Q. I understand that. So is

1 the answer no, you wouldn't be able to
2 provide me with a list of search terms?

3 MS. RELKIN: Objection.

4 Asked and answered.

5 THE WITNESS: I think that
6 the question is a misunderstanding
7 of the methodology that I used for
8 this review.

9 BY MR. HERMAN:

10 Q. Professor Keyes, you opined
11 that prescription opioid use is causally
12 related to subsequent heroin use, right?

13 A. Let me find the specific --
14 so I say prescription opioid use is also
15 causally related to subsequent heroin
16 use.

17 Q. Okay. And that's your
18 opinion?

19 A. Yes.

20 Q. Did you rely on the studies
21 discussed in Section B.7 of your report
22 to reach that conclusion?

23 A. Yeah. Section B.7 is the
24 section on the causal relationship

1 between prescription opioid use and
2 heroin use.

3 Q. Okay. And so your opinion
4 relied -- excuse me. Strike that.

5 Your opinion that
6 prescription opioid use is causally
7 related to subsequent heroin use relies
8 on the studies discussed in Section B.7?

9 MS. RELKIN: Objection to
10 form.

11 THE WITNESS: Let me just
12 read the question again. Your
13 opinion that prescription opioid
14 use is causally related to
15 subsequent heroin use relies on
16 studies discussed in Section B.7.

17 Section B.7 is where I
18 provide an overview of the
19 evidence that formed my opinion,
20 yes.

21 BY MR. HERMAN:

22 Q. And is there any evidence
23 that formed your opinion that's not
24 discussed in Section B.7?

1 A. The evidence that formed my
2 opinion was discussed in B.7.

3 Q. You haven't done any studies
4 on whether there is a causal connection
5 between prescription opioid use and
6 heroin use?

7 A. My expertise is in
8 epidemiology, and part of that expertise
9 is in evaluating the literature, which I
10 do as part of my routine epidemiological
11 work, and that forms the opinion that I
12 made.

13 Q. You relied on a set of
14 observational descriptive studies
15 conducted by others?

16 A. Can you define what you mean
17 by observational and descriptive?

18 Q. Well, would you describe the
19 studies that you relied on differently
20 than as observational and descriptive
21 studies?

22 A. I just want to make sure
23 that the terminology we're using is
24 consistent.

1 So let's see. Let me just
2 go through the studies that I cited. So
3 these studies were observational as
4 opposed to experimental. There's no --
5 been no study where individuals have been
6 randomized to high levels of prescription
7 opioids and observed to see whether there
8 is subsequent transition to heroin use.

9 These - the data cited in
10 this section rely on observations of
11 individuals who use prescription opioids
12 and use heroin.

13 Q. Which studies -- I'm not
14 asking for a description of the studies,
15 just names -- were the most important to
16 your analysis?

17 A. The studies that I found
18 particularly compelling, one is cited in
19 Figure 2, I believe it is. Figure 2 is
20 "The fitted hazard ratios of heroin
21 initiation associated with prior
22 non-medical prescription opioid use by
23 age of non-medical prescription opioid
24 use initiation."

1 And then there were two
2 others that I would particularly point to
3 as -- I mean, I think the body of
4 evidence speaks for itself. And, you
5 know, if I were to pick up particular
6 studies, I think Muhuri et al., Reference
7 97, also used the National Household
8 Survey on Drug Use and Health, I think
9 provides a high level of evidence.

10 I think the Cicero study
11 that I prescribe in the previous
12 paragraph. And I -- I mean, frankly all
13 of the studies are -- together form the
14 evidence base.

15 There's another one that's
16 really good. That's not to say that the
17 other studies that I'm not highlighting
18 here are flawed in any way. It's just --
19 oh, Banerjee, et al., 2016.

20 I think those studies I
21 would particularly highlight. But,
22 again, I think all of the studies formed
23 an evidence base that together make a
24 very compelling case.

1 Q. And the studies that you
2 discuss in B.7 of your report looked at
3 whether an association exists between
4 nonmedical use of prescription opioids
5 and heroin use?

6 A. No, that's not the case. I
7 believe some of the studies that were
8 cited don't differentiate between
9 nonmedical and medical use.

10 Q. Okay. Are you aware of a
11 study that has established an association
12 between medical use of prescription
13 opioids and heroin?

14 A. We can go through each of
15 the studies.

16 Q. Well, I'm just asking you.
17 Do you recall a study that established an
18 association between medical use of
19 prescription opioids and heroin?

20 A. I mean, the question itself,
21 you know, there's an established
22 association between medical use and
23 nonmedical use.

24 So these -- for example, the

1 studies in the National Household Survey
2 of Drug Use and Health specifically
3 queries nonmedical use of prescription
4 opioids. But that doesn't -- that
5 doesn't mean nonmedical use only in
6 individuals in the National Household
7 Survey and Drug Use and Health can be
8 using medically. And further, there's a
9 lot more data that I cited in this report
10 about the connection between medical use
11 and subsequent nonmedical use in the
12 earlier section.

13 So I think on balance I
14 would feel confident in saying that
15 prescription opioid use, regardless of
16 the origination of the source, is
17 causally associated with heroin use.

18 Q. Are you familiar with the
19 percentage of people who use prescription
20 opioids in accordance with their
21 prescriptions who later use heroin?

22 MS. RELKIN: Objection to
23 form.

24 THE WITNESS: I'm just going

1 to read the question out loud
2 again.

3 "Are you familiar with the
4 percentage of people who use
5 prescription opioids in accordance
6 with their prescriptions who later
7 use heroin?"

8 So the studies that are
9 cited in this -- in this section
10 in particular, report a wide range
11 of, you know, we can go through
12 each of the different 16 studies
13 that I have reviewed.

14 A lot of those studies are
15 among heroin users. And so
16 they -- people are reporting on
17 their past histories of nonmedical
18 and/or medical use.

19 BY MR. HERMAN:

20 Q. I'm asking you a more
21 specific question. Are you familiar with
22 the percentage of people who use
23 prescription opioids in accordance with
24 their prescription who later use heroin?

1 MS. RELKIN: Do you want her
2 to go through her studies, the
3 studies cited, to address that?

4 THE WITNESS: Yeah,
5 that's --

6 MR. HERMAN: No, I want her
7 to answer my question. Is she
8 familiar with...

9 THE WITNESS: I think we
10 need to go to the evidence base in
11 order to answer that question.

12 BY MR. HERMAN:

13 Q. You can't -- you can't
14 answer that question?

15 A. There -- there are 16
16 studies that are cited in this section.

17 Q. Okay.

18 A. Shall I get the --

19 Q. No.

20 A. Okay.

21 Q. Do you agree that
22 prescription opioid use is not necessary
23 for the initiation of heroin use?

24 A. Do you agree with...

1 So this question, I think,
2 gets to the concept of risk factors which
3 is what I outlined in -- in the beginning
4 of the report in terms of how we define
5 risk factors in terms of causal
6 associations in epidemiology.

7 MS. RELKIN: Objection to
8 form.

9 THE WITNESS: So a lot of
10 risk factors are what we call
11 unnecessary insufficient causes.
12 So while certainly there are
13 heroin users that didn't start
14 with prescription opioids,
15 prescription opioid increases
16 the -- prescription opioid use
17 increases the risk of subsequent
18 transition to heroin use.

19 BY MR. HERMAN:

20 Q. But you agree that
21 prescription opioid use is not necessary
22 for the initiation of heroin use?

23 A. Again, the -- I would
24 point --

1 MS. RELKIN: Objection to
2 form.

3 THE WITNESS: -- to the
4 concept of a risk factor. And so
5 it increases the risk, and it is
6 not necessary. Just like smoking
7 increases the risk of lung cancer,
8 but there's a lot of lung cancer
9 cases of individuals who didn't
10 smoke. It doesn't make cigarettes
11 any less of a cause.

12 BY MR. HERMAN:

13 Q. Do you agree that
14 prescription opioid use is not sufficient
15 for the initiation of heroin use?

16 MS. RELKIN: Objection to
17 form.

18 THE WITNESS: This also
19 points to the concept of risk
20 factors. Just like there's many
21 smokers who never develop lung
22 cancer doesn't make smoking any
23 less of a cause. There are many
24 risk factors in epidemiology that

1 are in and of themselves
2 insufficient and unnecessary. But
3 the evidence is clear that they
4 are causally related to outcomes
5 of interest. And I would put
6 prescription opioids in that
7 category.

8 BY MR. HERMAN:

9 Q. Do any of the articles that
10 you cite conclude that there is a causal
11 relationship between prescription opioid
12 use and heroin use?

13 A. So, you know, I think in
14 developing an evidence base, this is how
15 science often progresses, is that you
16 build a body of work around a
17 different -- around a particular topic.

18 So it -- again, if -- if
19 any -- if it was just one of these
20 studies that suggested a relationship
21 between prescription opioid use and
22 heroin use, I think the evidence base
23 would be much less clear.

24 But given the weight of the

1 evidence that is described in that
2 section, I think my scientific opinion is
3 that there is a causal relationship
4 between prescription opioid use and
5 heroin use.

6 And it's not based on any
7 one particular study. It's based on
8 the -- the weight of the evidence.

9 Q. But you would agree that
10 none of the articles that you cite
11 conclude that there is a causal
12 relationship between prescription opioid
13 use and heroin use?

14 MS. RELKIN: Objection to
15 form.

16 THE WITNESS: So what I
17 would agree with is that someone
18 trained in epidemiology who is
19 evaluating the evidence, would
20 conclude that there is a causal
21 relationship between prescription
22 opioid use and heroin use. Any
23 one particular study doesn't make
24 that case, it's the body of

1 evidence.

2 BY MR. HERMAN:

3 Q. And none of the studies that
4 you cite conclude that there is a causal
5 relationship between prescription opioid
6 use and heroin use, correct?

7 MS. RELKIN: Objection to
8 form.

9 THE WITNESS: Again, I -- I
10 think any one particular study is
11 not sufficient to make that kind
12 of claim. What can make a claim
13 is the body of evidence that is
14 evaluated.

15 And so I evaluated the body
16 of evidence and made -- came to
17 the conclusion that there is a
18 causal relationship.

19 BY MR. HERMAN:

20 Q. You agree that only a small
21 portion -- a small portion of people who
22 use prescription opioids later use
23 heroin?

24 MS. RELKIN: Objection to

1 form.

2 THE WITNESS: Prescription
3 opioid use increases the risk of
4 subsequent transition to heroin
5 use. Heroin use is relatively
6 rare in the population.

7 Prescription opioid use is
8 relatively common. So because of
9 those two things, you know,
10 that -- that underlies the concept
11 of risk factors. That relatively
12 common exposures can influence
13 relatively rare outcomes.

14 BY MR. HERMAN:

15 Q. But you agree that it's a
16 rare outcome that a prescription opioid
17 user later uses heroin?

18 A. I wouldn't say it's a --

19 MS. RELKIN: Objection.

20 Asked and answered.

21 THE WITNESS: Well, I --

22 I -- what I would qualify that
23 with is the data on the number of
24 heroin users there are in the

1 United States, which is provided
2 in -- I'm sure it's in that
3 section.

4 So as of 2010, available
5 estimates were that there's
6 1.5 million individuals in the
7 U.S. using heroin at least four
8 times a month or more. And so
9 there's probably even more heroin
10 users that are using less than
11 four times per month. It's just
12 that prescription opioid use is
13 more common than that.

14 BY MR. HERMAN:

15 Q. I don't think that answered
16 my question.

17 My question was, but you
18 agree that it's a rare outcome that a
19 prescription opioid user later uses
20 heroin?

21 MS. RELKIN: Objection to
22 form.

23 THE WITNESS: I would have
24 to qualify that statement by what

1 you mean by rare. I mean the
2 orders of magnitude of the
3 increase in risk that I cite in
4 this paper are -- indicate that
5 there -- there is a much higher
6 risk of transitioning to heroin
7 use given that you've used a
8 prescription opioid.

9 Heroin use overall in the
10 general population is 1.5 million.
11 Perhaps slightly more if you count
12 less than four times per month.

13 So as a general health
14 outcome, prescription opioid use
15 is more common than heroin use.
16 So the statement that it is rare
17 to transition, I don't think is
18 accurate.

19 BY MR. HERMAN:

20 Q. Do you agree that the
21 absolute risk of transitioning to heroin
22 given prescription opioid use is relative
23 live small?

24 A. That is a statement that I

1 wrote in my report.

2 Q. Okay. So you'll agree with
3 that?

4 A. I would agree with the
5 statement that I wrote in my report which
6 is -- hold on. Let me just pull it up to
7 make sure that I'm describing the method
8 appropriately.

9 Can you point to the page
10 number, please?

11 Q. Page 27.

12 A. Okay.

13 Q. And I'm asking you --

14 A. A small proportion of
15 individuals who use prescription
16 opioids progress to heroin use. That's
17 correct.

18 There is -- prescription
19 opioid use is much more common than
20 heroin use. So in order to explain the
21 increase in heroin use, only a small
22 proportion of opioid users need to
23 transition in order to explain that
24 increase. That's the context for the

1 statement.

2 I mean, the next sentence
3 gives you some indication that
4 individuals who use prescription opioids
5 are approximately seven times larger than
6 the number of individuals who use heroin.
7 So it only takes a small number of users
8 transitioning to create the opioid
9 epidemic that we observed in the last
10 several years.

11 Q. Are you familiar with
12 analysis that shows that individuals who
13 use prescription opioids nonmedically to
14 self-medicate pain are less likely to
15 later use heroin?

16 A. Are you familiar with the
17 analysis -- this is one particular
18 analysis?

19 Q. I'm sorry. Are you familiar
20 with analysis that shows that individuals
21 who use prescription opioids nonmedically
22 to self-medicate pain are less likely to
23 later use heroin?

24 MS. RELKIN: Objection to

1 form.

2 THE WITNESS: Less likely
3 than whom?

4 BY MR. HERMAN:

5 Q. Less likely than individuals
6 who are using prescription opioids
7 nonmedically to get high?

8 A. I would have to look at the
9 methodology of the analysis, because I
10 don't understand what self-medicate pain
11 specifically means and how that's
12 measured. Okay. Do you have an analysis
13 that you can provide?

14 Q. No. I'm just asking, you're
15 not familiar with analysis that shows
16 that people that are --

17 A. I don't --

18 Q. -- that use prescription
19 opioids nonmedically to self-medicate
20 pain are less likely to later use heroin?

21 A. Again, I don't -- I don't
22 understand the comparison group. I don't
23 know what self-medicate pain means in
24 that circumstance. So if there's

1 something to look at, I can look at it.

2 But nothing that I evaluated in this body
3 of work has -- looks at self-medicating
4 pain in that way.

5 Q. Are individuals who
6 frequently use prescription opioids
7 nonmedically for the high the most likely
8 to later use heroin?

9 MS. RELKIN: Objection to
10 form.

11 THE WITNESS: Can you define
12 what you mean by "for the high"?

13 BY MR. HERMAN:

14 Q. For the euphoric feeling.

15 A. I would have to, again,
16 based on the epidemiological evidence
17 that I reviewed and my personal knowledge
18 about the literature on motivation to use
19 all kinds of drugs, including
20 prescription opioids, the whole concept
21 of euphoria is really difficult to
22 measure in the medical literature and in
23 the nonmedical prescription opioid
24 literature.

1 So to make that kind of
2 claim, you would need strong data, and I
3 would need to see data that made that
4 kind of claim in order to evaluate that
5 statement.

6 Q. Would you agree that
7 individuals who frequently use
8 prescription opioids nonmedically are
9 more likely to later use heroin?

10 MS. RELKIN: Objection to
11 form.

12 THE WITNESS: So that
13 evidence, evidence regarding that
14 question is in the report,
15 including that there is a
16 dose-response relationship between
17 the frequency of prescription
18 opioid use and the risk of
19 transition to heroin use.

20 So I would say -- I'm sorry.
21 You said prescription opioid
22 nonmedically.

23 So the data that's used to
24 make that statement, for example,

1 in the National Household Survey
2 on Drug Use and Health, they
3 specifically query nonmedical use,
4 but I doesn't exclude medical
5 users.

6 So I would not agree with
7 your statement that individuals
8 who frequently use prescription
9 opioids non-medically are more
10 likely to later use heroin.

11 I would say that the body of
12 literature indicates that people
13 who use prescription opioids
14 frequently are more likely to
15 transition to heroin than people
16 who use prescription opioids
17 non-frequently --

18 BY MR. HERMAN:

19 Q. And it's your testimony
20 that --

21 A. -- infrequently.

22 Q. -- that the body of
23 literature that you looked at went beyond
24 nonmedical use of prescription opioids?

1 A. I think that the available
2 literature that I have assessed in this
3 report indicates that a substantial
4 portion of nonmedical users -- and I
5 think I've cited some of the studies
6 already in this deposition, received
7 legitimate prescriptions from providers
8 at some point so a differentiation
9 between someone who's only ever used
10 opioids nonmedically and someone who used
11 both medically and nonmedically, I think,
12 is not -- we're not separating out people
13 who've only used opioids nonmedically.
14 The vast majority of individuals who use
15 opioids nonmedically obtain a
16 prescription at some point.

17 Q. But do you recall any of the
18 studies that you looked at that
19 specifically look at medical use of
20 prescription opioids?

21 A. So again I can pull out the
22 studies because a lot of the studies
23 include assessments of heroin users
24 who've -- the percentages who have

1 received prescription opioids from a
2 doctor.

3 Q. All right. Heroin use was
4 prevalent in the 1960s and 1970s, right?

5 MS. RELKIN: Objection to
6 form.

7 THE WITNESS: What do you
8 mean by prevalent? I have from
9 the '60s and '70s that the number
10 of individuals using heroin in the
11 U.S. was approximately 100,000.

12 BY MR. HERMAN:

13 Q. And do you recall that the
14 Cicero article that you cite discusses
15 that among persons who began opioid use
16 in the 1960s, more than 80 percent
17 reported that their first opioid was
18 heroin?

19 A. I'm going to have to pull
20 the article out to --

21 Q. Okay. Why don't we mark it.

22 A. 84 is not in here. Cicero
23 is 86, right?

24 Q. I'm going to hand you a

1 copy.

2 A. Okay.

3 Q. We'll mark it.

4 (Document marked for
5 identification as Exhibit
6 Keyes-8.)

7 BY MR. HERMAN:

8 Q. I'm handing you the Cicero
9 article that's been marked as Exhibit 8.

10 A. And so there's a sentence in
11 here to evaluate?

12 Q. Yeah. Under results.
13 "Respondents who began using heroin in
14 the 1960s were predominately young men
15 whose first opioid abuse was heroin."

16 A. I can't read the results
17 section in this copy. I can pull up my
18 version. But this is all fuzzy.

19 Q. Why don't you pull your
20 version, but it's actually on the front
21 page.

22 MS. RELKIN: She wants to --

23 THE WITNESS: Well, the
24 abstract is one thing --

1 MS. RELKIN: She wants to be
2 sure.

3 THE WITNESS: -- but I'd
4 like to go to the results.

5 Let me just make sure this
6 is the same article.

7 Okay. So you had a comment
8 on the results section of the
9 abstract?

10 BY MR. HERMAN:

11 Q. Yes.

12 A. Respondents who began using
13 heroin in the 1960s...

14 Okay. So these are data
15 from the -- from the sample called SKIP,
16 survey of Key Informants Patients
17 program.

18 So this is 150 publicly and
19 privately funded treatment centers.

20 And so this is individuals
21 who met DSM-IV criteria for substance
22 abuse of the primary drug of prescription
23 opioids or heroin.

24 And so I'm just trying to

1 see how they ask this question.

2 Okay. So the SKIP
3 respondents were asked to identify the
4 opioid most frequently used in the last
5 month, how often they abuse, what age
6 they began abusing regularly.

7 Okay. So now the question
8 is, among those who started using in the
9 1960s, the percentage of the
10 heroin-dependent sample that used heroin
11 first was 80 compared to -- a little over
12 80 compared to 20. That's correct.

13 Q. Professor Keyes, you said
14 this was one of the studies that you
15 relied on, right?

16 A. Yes.

17 Q. And, Professor Keyes, you
18 were an author on an article that was
19 published in January of 2018?

20 A. Wait, can we -- I'm sorry.
21 I didn't realize that we were leaving
22 this paper. I just want to comment that
23 the percentage of individuals who use
24 prescription opioids before heroin

1 increased with every single decade
2 commensurate with the increase in the
3 prescription opioid supply, from 1980 to
4 1990, to 2000. So I think that focusing
5 only on the 1960 cohort obfuscates the
6 point of the analysis, which is that
7 there was an increase in the percentage
8 who used prescription opioids first among
9 that heroin dependent sample.

10 Q. Well, I appreciate that.

11 A. So I want to make sure that
12 that's clear.

13 Q. Now, in the abstract on --
14 well, on Page 26 of your report you said
15 that this study shows that 85 percent of
16 heroin users began with prescription
17 opioids in 2010, and 78 percent -- or I'm
18 sorry. 85 percent in 2000 and 78 percent
19 in 2010, right?

20 A. So I say, "From the 1990s
21 on, as the supply of opioids increased,
22 so too did the proportion of individuals
23 who used heroin who began opioids use
24 with prescription opioids." And then I

1 listed the percentages in Cicero for each
2 of the decades.

3 Q. And if you want to set that
4 article aside.

5 You were an author on an
6 article that was published in
7 January 2018 that stated that the
8 incidence of heroin use among those who
9 were naive to prescription opioids had
10 increased. Do you recall that?

11 A. I need to know which paper
12 you're talking about. I publish a lot of
13 papers.

14 Q. You don't recall being an
15 author on a paper that --

16 A. I would like to see the
17 paper and the context in which that
18 statement was made.

19 Q. Well, I'm just asking you if
20 you recall writing a paper that the
21 incident of heroin --

22 A. I -- I --

23 Q. -- use among --

24 A. Unless I understand the

1 context of the statement, I'm -- I need
2 to see the paper.

3 Q. Are you aware of literature
4 that shows that the incidence of heroin
5 use among those who were naive to
6 prescription opioids has increased?

7 A. Heroin use has increased
8 among -- and there's certainly more of an
9 increase among -- and there's numerous
10 papers, I think I cite Compton in here in
11 particular, that show that heroin use has
12 increased more among prescription opioid
13 users.

14 Q. Well, that wasn't my
15 question.

16 I'm asking you, are you
17 aware of literature that shows that the
18 incidence of heroin use among those who
19 were naive to prescription opioids has
20 increased?

21 A. Again, I don't think you can
22 evaluate that statement without the
23 entire context, which is that heroin use
24 has gone up overall, and more so among

1 those who use prescription opioids.

2 Q. Okay. Well, just listen to
3 my question. Are you aware of literature
4 that says that the incidence of heroin
5 use among those who are naive to
6 prescription opioids has increased?

7 A. I think I've answered the
8 question.

9 Q. You've certainly given me
10 your view --

11 MS. RELKIN: There's more
12 than -- if you want to show her --
13 BY MR. HERMAN:

14 Q. -- but I'm asking you
15 whether you are aware of literature that
16 shows that the incidence of heroin use
17 among those who are naive to prescription
18 opioids has increased.

19 A. The incidence of heroin use
20 has increased among both prescription
21 opioid users and individuals who have
22 never used prescription opioids, has
23 increased more among prescription opioid
24 users. Heroin use overall has gone up.

1 Q. I'm asking you -- maybe I
2 should rephrase my question.

3 Are you aware that the
4 percentage of individuals using heroin --
5 or excuse me. Are you aware that the
6 percentage of heroin users who are opioid
7 naive to prescription opioids has
8 increased?

9 MS. RELKIN: Objection to
10 form.

11 THE WITNESS: My assessment
12 of the epidemiological literature
13 is that heroin use overall has
14 increased across groups of
15 individuals who have both used and
16 haven't used prescription opioids,
17 and it's gone up more among people
18 who use prescription opioids.

19 BY MR. HERMAN:

20 Q. Are you aware that Cicero
21 reported in the 2018 article that
22 described heroin use as a first opioid --
23 that described how heroin use as a first
24 opioid grew from 8.7 percent in 2005 to

1 almost 31.6 percent at 2016 --

2 A. I need to see the article.

3 Q. You are not aware of that
4 article?

5 A. I -- I need to evaluate the
6 article in order to know -- I don't know
7 the -- the facts and figures in Cicero
8 2018 off the top of my head.

9 Q. But you believe that
10 Cicero's -- this article was a reliable
11 source that you used?

12 MS. RELKIN: Objection to
13 form.

14 THE WITNESS: I'm not going
15 to make a statement about a paper
16 that I don't have in front of me.

17 BY MR. HERMAN:

18 Q. Did you consider the fact
19 that the incidence of heroin use among
20 those who are naive to prescription
21 opioids is increasing in your causal
22 analysis?

23 A. So risk factor epidemiology
24 has a frame for evaluating the causal

1 relationships between exposures and
2 outcomes. Oftentimes includes
3 assessments of factors that are neither
4 necessary nor sufficient.

5 So again to use the smoking
6 in lung cancer example, because I think
7 we can all agree that smoking causes lung
8 cancer. There are people who have lung
9 cancer who have never smoked. That
10 doesn't preclude cigarette smoking from
11 being a cause of lung cancer.

12 Similarly, there are people
13 who -- who use heroin who might never
14 have used a prescription opioid. That
15 doesn't make prescription opioids any
16 less of a cause.

17 Q. Wouldn't it change your
18 80 percent figure?

19 MS. RELKIN: Objection to
20 form.

21 THE WITNESS: Can you
22 describe your methodology for
23 that?

24 BY MR. HERMAN:

1 Q. Well, if more people were
2 using heroin as their opioid of first
3 use, wouldn't the percentage of people --

4 A. I need to see the paper in
5 front of me in order to evaluate that
6 statement.

7 Q. Let me finish my question
8 please.

9 If you're starting with, as
10 you report, that 80 percent of people
11 transition from heroin -- from
12 prescription opioids to heroin --

13 A. That's not -- sorry. You
14 can continue. But I disagree with that.

15 Q. Okay.

16 -- wouldn't you -- wouldn't
17 the percentage of people who are using
18 heroin as their first opioid matter to
19 that calculation?

20 A. Those are two different
21 research questions.

22 Q. Okay.

23 Can I ask you to flip to
24 Page 3. And on Page 3 you say, in the

1 second -- sorry, the third bullet, that
2 approximately 80 percent of heroin users
3 in the last two decades used prescription
4 opioids before heroin use?

5 A. That's what it says.

6 Q. Okay. And can you flip back
7 to Page 26. And if you look at the
8 second paragraph, the first sentence, you
9 say, "The available data consistently
10 shows that approximately 70 to 80 percent
11 of individuals who used heroin in the
12 last 20 years started their opioid use
13 with prescription opioids."

14 Do you see that?

15 A. Yes.

16 Q. Okay. Are you using
17 approximately 80 percent for your
18 opinion, or 70 to 80 percent?

19 MS. RELKIN: Objection to
20 form.

21 THE WITNESS: I would defer
22 to what is actually in the report,
23 the 70 to 80 percent.

24 BY MR. HERMAN:

1 Q. Okay.

2 A. It's closer to 80 percent
3 across the studies, but I think the more
4 conservative evaluation of the literature
5 would be 70 to 80.

6 Q. Okay. And what's the
7 20-year time period that you're looking
8 at?

9 A. I would say that the
10 majority of the literature that I
11 evaluated was 1990 to now. So the past
12 two plus decades.

13 Q. Okay. So the time period
14 you're looking at goes from 1990 to the
15 present?

16 MS. RELKIN: Objection to
17 form.

18 THE WITNESS: Probably late
19 1990s to the present. That's the
20 last 20 years. We are in 2018.
21 So late 1990s to the present.

22 BY MR. HERMAN:

23 Q. You opine that the abuse of
24 prescription opioids is causally tied to

1 the increase in the supply of
2 prescription opioids, right?

3 A. You opine that the abuse of
4 prescription opioids is causally tied to
5 the increase of supply -- yes, that is
6 correct.

7 Q. What, if anything, did you
8 do to investigate trends in the supply of
9 nonprescription illicit opioids?

10 MS. RELKIN: Objection to
11 form.

12 THE WITNESS: So the
13 available epidemiological
14 literature that I have
15 predominately uses opioid
16 distribution data as an exposure.

17 The data on supply of other
18 kinds of opioids is more difficult
19 to collect, because it is a black
20 market.

21 BY MR. HERMAN:

22 Q. Are you aware of changes in
23 the quantity of heroin in the United
24 States?

1 A. I'm aware that there are --
2 MS. RELKIN: Objection to
3 form.

4 THE WITNESS: -- data -- I
5 am aware that there have been
6 attempts to evaluate.

7 BY MR. HERMAN:

8 Q. Are you aware that the
9 supply of heroin has increased in the
10 United States?

11 A. I would need to see the
12 source of data that you're using to make
13 that statement.

14 Q. Okay. Not something that
15 you looked into?

16 MS. RELKIN: Objection to
17 form.

18 THE WITNESS: If you have a
19 specific document that I should
20 evaluate, I would be happy to
21 evaluate. What I've done here is
22 looked at the epidemiological
23 literature. If there's a
24 different source that's not in the

1 epidemiological literature that I
2 reviewed, I cannot speak to it
3 unless I see the document.

4 BY MR. HERMAN:

5 Q. Are you aware whether the
6 distribution network for heroin in the
7 United States has become more widespread?

8 A. I would need to see the
9 document that you're using or source of
10 data.

11 Q. Are you aware whether the
12 price of heroin in the United States has
13 decreased?

14 MS. RELKIN: Objection to
15 form.

16 THE WITNESS: Did -- I mean,
17 what data provide that assessment?
18 Because I reviewed the
19 epidemiological literature.

20 BY MR. HERMAN:

21 Q. I'm just asking if you're
22 aware. Are you aware one way or the
23 other if the price of heroin in the
24 United States has decreased?

1 A. There are data sources that
2 attempt to evaluate that position, but
3 there's a lot of measurement error in
4 trying to assess price. So I would need
5 to see, if someone were to make that
6 statement, I would need to see the source
7 of data in order to evaluate whether it's
8 epidemiologically rigorous.

9 (Document marked for
10 identification as Exhibit
11 Keyes-9.)

12 BY MR. HERMAN:

13 Q. I'm handing you what's been
14 marked as Keyes Exhibit 9. It's a
15 Lankenau study that you reference in your
16 report.

17 A. Yes.

18 Q. Okay. And this study looked
19 at 50 injection drug users who had used
20 prescription drugs at least three times
21 in the past three months; is that
22 correct?

23 I'll direct your attention
24 to the first page, "Methods: Those young

1 IDUs who misused a prescription" --

2 A. Yeah, I -- I just want to
3 read it in the actual methods section
4 because sometimes things can be over
5 simplified in an abstract. So study
6 eligibility was based on three criteria:
7 Aged 16 to 25, misused a prescription
8 drug at least three times in the past
9 three months, and had injected a drug
10 within the past three months.

11 Q. Okay.

12 A. So those are the three
13 eligibility criteria.

14 Q. So the requirements for
15 being in the study were an age
16 requirement, right?

17 A. 16 to 25 years old.

18 Q. The second requirement was
19 that you had used a prescription drug
20 three times in the past three months,
21 correct?

22 A. Yes.

23 Q. And the third requirement
24 was that you were an injection drug user?

1 A. You had injected a drug
2 within the past three months.

3 Q. Wouldn't you expect to find
4 a higher number of individuals who used
5 prescription drugs before heroin use in a
6 population that required both
7 prescription drug use three times in the
8 past month and injection users?

9 MS. RELKIN: Objection to
10 form.

11 THE WITNESS: I mean, this
12 is why we do research because we
13 don't know what we expect to find
14 before we do the research. And so
15 this particular paper is evaluated
16 within a larger body of
17 literature. So what you expect
18 is -- you have to do the research
19 in order to determine what you
20 would expect.

21 BY MR. HERMAN:

22 Q. You don't think that the
23 selection criteria made it more likely
24 that you would find people who were using

1 both prescription drugs and who were
2 heroin users?

3 MS. RELKIN: Objection to
4 form.

5 THE WITNESS: I think I've
6 answered the question.

7 BY MR. HERMAN:

8 Q. I'm handing you Keyes
9 Exhibit 10.

10 (Document marked for
11 identification as Exhibit
12 Keyes-10.)

13 BY MR. HERMAN:

14 Q. Which is the Mateu-Gelabert
15 study that you referenced in your report.
16 And if I could direct your attention to
17 the methods description on Page 3.

18 A. Yes.

19 Q. And this is a study that
20 involved 46 New York young adults who
21 engaged in nonmedical prescription drug
22 use, right?

23 A. Prescription opioid use.

24 Q. Prescription opioid use.

1 And half the participants
2 were referred by service providers,
3 including an outreach program for young
4 injectors, right?

5 A. Drug treatment programs, an
6 outreach program for young injectors, key
7 informants or other research projects are
8 the sources.

9 Q. Okay. And so you'd agree
10 some unknown percentage of this
11 population was recruited from a service
12 provider program for young injectors?

13 A. I would agree that there
14 were five sources of data selection.
15 They were drug treatment programs, an
16 outreach program for young injectors, key
17 informants, other research projects, and
18 the remaining other participants were
19 recruited via chain referral from other
20 participants.

21 Q. Okay. And chain referral
22 means that some of the people who had
23 been recruited referred other people?

24 A. That's typically what chain

1 referral refers to.

2 Q. Okay. You would agree that
3 there were studies that you discussed in
4 your report that show a lower percentage
5 of heroin users use prescription opioids
6 before heroin than the 70 to 80 percent
7 figure that you use, right?

8 MS. RELKIN: Objection to
9 form.

10 THE WITNESS: You would
11 agree that there were studies that
12 you discussed in your report that
13 show a lower percentage.

14 If there is a particular
15 study that I should --

16 BY MR. HERMAN:

17 Q. Well, for example you
18 discuss the Pollini study, correct?

19 A. Which reference number?

20 Q. Well, I'll refer you to Page
21 26 of your report. You say, "Pollini, et
22 al., studied 123 individuals who injected
23 heroin, documenting a 39.8 percent
24 reported prescription opioid use prior to

1 heroin use."

2 A. I'm going to get the paper.

3 Q. That's not what you wrote in
4 your report.

5 A. This is what I wrote in the
6 report, but if you are asking me a
7 question about the paper, I want to see
8 the paper before I answer the question.

9 Q. Okay. You don't recall
10 whether there were studies that show a
11 lower percentage of heroin users who used
12 prescription opioids before heroin in the
13 70 to 80 percent figure that you're
14 using?

15 A. So I'm going to look at this
16 study.

17 Q. Well, before you do that,
18 I'm just asking if you recall.

19 A. I'm sorry. What was the
20 question?

21 You don't recall whether
22 there were studies that show a lower
23 percentage of users who use prescription
24 opioids before heroin.

1 You know, there's 200
2 citations in this report. If I'm being
3 asked a specific question about a piece
4 of evidence, I'd like to review the
5 material before answering the question.

6 Q. You've talked several times
7 today about how persuasive those 16
8 studies were that you reviewed, right?

9 A. I said that there was a body
10 of evidence and that that body of
11 evidence together made a compelling case.

12 Q. And you carefully reviewed
13 those 16 studies?

14 A. I reviewed the 16 studies.

15 Q. Okay.

16 A. Do you want immediate to
17 read this paper and talk about the
18 figure? 39.8 percent?

19 Q. Go ahead.

20 I direct you -- I believe --
21 you can look through it. But I believe
22 it's on Page 180 -- 178. It's where it
23 discussed the results.

24 A. Okay. So this paper needs

1 to be a bit qualified because as you will
2 read in the methods section, the question
3 that was asked was, "Before you began
4 using heroin, were you hooked on
5 prescription-type opioids?"

6 "Those who answered
7 affirmatively were then asked, 'Which
8 prescription-type opioids were you hooked
9 on?'"

10 So those are the measures
11 that we're looking at.

12 And then in the results
13 section --

14 Q. Well, I'll direct you to
15 this -- the conclusion. The
16 conclusion --

17 A. No, I would like to look at
18 the results. I'm sorry, I'm -- I just
19 want to see where these numbers are
20 coming from before drawing a conclusion.

21 Q. Well, why don't I read you
22 the conclusion while you do that. It
23 says, "In this" --

24 MS. RELKIN: Well, she

1 can't -- she has to -- she's
2 reading, she can't listen.

3 So let her read it and then
4 you can ask your question.

5 THE WITNESS: Okay. I'm
6 just trying to find this
7 30 percent.

8 Okay. So they defined these
9 groups as "characteristics of
10 heroin injectors who responded
11 affirmatively to the question
12 about being hooked on
13 prescription-type opioid use."

14 So the 39.8 percent cited in
15 the report is individuals who
16 injected heroin who are first
17 hooked on prescription-type
18 opioids.

19 So it's not necessarily
20 germane to individuals who started
21 using opioids, prescription
22 opioids for their opioid using
23 career.

24 BY MR. HERMAN:

1 Q. But you'd agree with me that
2 the conclusion states, "In this study of
3 young heroin IDUs in San Diego,
4 California, we found that 40 percent
5 reported problematic use of prescription
6 type opioids prior to initiating heroin
7 use. Similar proportions of prior
8 problematic prescription-type opioid use
9 have been reported in studies of young
10 heroin IDUs in Portland, Oregon,
11 47 percent, and Seattle, Washington,
12 44 percent."

13 A. So I think these are two
14 different research questions. One
15 research question is about individuals
16 who are using the -- the proportion who
17 used prescription opioids prior to
18 heroin. I think these studies speak to a
19 different research question, which is the
20 proportion who were hooked on
21 prescription opioids prior to heroin.

22 And I would need to look at
23 References 12 and 13 to make statements
24 about those particular studies. I'm only

1 speaking to this Pollini article.

2 References 12 and 13 are
3 another Pollini article that was not a
4 peer-reviewed paper. It was a late
5 breaker abstract at CPDD from the same
6 sample. It looks like. I would have to
7 look at it again to make -- be sure.

8 And then the other one is
9 also not a peer-reviewed paper. It is a
10 paper called "Drug Abuse Trends in the
11 Seattle King County Area 2009," that was
12 in the proceedings of a working group.

13 So I don't know that I can
14 really make conclusions about those
15 percentages based on an abstract in a
16 working group paper.

17 Q. Okay. But you would agree
18 with me that there are studies in papers
19 that report lower percentages of --

20 A. No, I would not agree.

21 Q. Okay. Do you think William
22 Compton is a well-regarded researcher?

23 MS. RELKIN: Objection to
24 form.

1 BY MR. HERMAN:

2 Q. I'm sorry, Wilson Compton.

3 A. I was going to say, William
4 Compton.

5 Q. My dad's named William.

6 A. Wilson Compton has published
7 in the peer-reviewed literature. In
8 order to establish the validity of any
9 one particular paper that Wilson Compton
10 participated in I would need to evaluate
11 it on a case-by-case basis.

12 Q. He is the deputy director of
13 the National Institute of Drug Abuse of
14 the National Institute of Health?

15 A. That's correct. Based on my
16 current knowledge.

17 Q. Okay. I'm going to hand you
18 an article by Wilson Compton that you
19 referenced in your report. It's been
20 marked as Keyes Exhibit 11.

21 (Document marked for
22 identification as Exhibit
23 Keyes-11.)

24 BY MR. HERMAN:

1 Q. And I direct your attention
2 to Page 156. And under the heading
3 "Heroin Use Among People Who Use
4 Prescription Opioids Nonmedically."

5 This article states that
6 "studies that address the patterns of
7 heroin use in nonmedical users of
8 prescription opioids are mostly
9 observational and descriptive, i.e.,
10 nonexperimental, thus conclusions about
11 cause and effect are uncertain."

12 Do you see that?

13 A. That is what is written
14 here.

15 Q. Do you disagree with
16 Dr. Compton's conclusions about the
17 ability to draw conclusions about cause
18 and effect from observational descriptive
19 studies he reviewed?

20 MS. RELKIN: Objection to
21 form.

22 THE WITNESS: We make causal
23 conclusions about observational
24 data in epidemiology frequently.

1 You have to build an evidence
2 base. No one particular study
3 from observational data allows you
4 to make a cause/effect conclusion
5 concretely, but when you build an
6 evidence base -- again, I would
7 point to smoking and lung cancer
8 for which there was never an
9 experimental study.

10 BY MR. HERMAN:

11 Q. Okay. Do you disagree with
12 Dr. Compton's conclusions about his
13 ability to draw a conclusion about cause
14 and effect from observational
15 descriptive -- observational descriptive
16 studies that he reviewed?

17 MS. RELKIN: Objection to
18 form. Are you talking about
19 conclusions from the top of the
20 paragraph or the bottom of the
21 paragraph?

22 MR. HERMAN: I'm talking
23 about the sentence that I -- that
24 we -- two sentences that we read

1 and agreed at the top of the
2 paragraph.

3 THE WITNESS: You know,
4 again, I think the evidence base
5 overall for this particular topic
6 is quite consistent in showing a
7 positive association, which is
8 what Compton states in that
9 paragraph. And that we use those
10 kinds of data in observational
11 epidemiology when we're drawing
12 conclusions.

13 BY MR. HERMAN:

14 Q. If you were writing for a
15 professional journal would you draw a
16 conclusion about causality from the
17 observational descriptive studies that
18 Dr. Compton looked at?

19 MS. RELKIN: Objection to
20 form.

21 THE WITNESS: So I do write
22 for professional journals. And I
23 have evaluated the literature in
24 this report. And I would draw the

1 conclusion in any forum, that the
2 available literature is consistent
3 with a causal association.

4 I mean, even Wilson Compton
5 in this sentence said that, "It's
6 highly suggestive and plausible
7 given their common pharmacologic
8 principles."

9 I think I would go a step
10 further given that we now have
11 three more years of data since
12 this was published.

13 BY MR. HERMAN:

14 Q. So you disagree with his
15 conclusion that -- his statement that
16 conclusions about cause and effect are
17 uncertain?

18 A. I would agree with his
19 conclusion that there is a positive
20 association, that it's highly suggestive
21 and plausible. And that given the
22 additional three years of publications
23 that I reviewed here, that there's
24 consistent evidence for a causal

1 association between prescription opioid
2 use and heroin use.

3 MS. RELKIN: Counsel, are
4 you directing to the conclusion
5 section where the conclusions
6 actually are?

7 MR. HERMAN: No. I asked
8 the questions that I asked.

9 MS. RELKIN: You referred to
10 a conclusion which was not in the
11 conclusion section, just for the
12 record.

13 BY MR. HERMAN:

14 Q. It says, "Thus, conclusions
15 about cause and effect are uncertain."

16 You would agree with that,
17 right? That's what it says there. Uses
18 the word "conclusion"?

19 A. Here in this paragraph, it
20 is written, "Thus, conclusions about
21 cause and effect are uncertain."

22 In the conclusions section,
23 it says that prescription opioids are a
24 strong risk factor for heroin use.

1 Q. And at the bottom of that
2 first column, he discusses a study that
3 found an Ohio 50 percent of persons 18 to
4 33 years of age who had recently begun
5 using heroin reported having abused
6 opioids, primarily OxyContin, before
7 initiating heroin use?

8 A. So I need to see the study.

9 Q. I'm just asking you if
10 that's what he reported at the bottom of
11 this first column onto the second column.

12 MS. RELKIN: If you are --

13 THE WITNESS: If you're
14 asking me what is written, I think
15 we can all agree what is written.
16 If you want me to look at the
17 study, I believe I cited it in my
18 report, and I can look at the
19 study and provide you with an
20 assessment of what that study
21 shows.

22 BY MR. HERMAN:

23 Q. And the percentage in that
24 study was less than the 80 percent that

1 you used in your report?

2 A. I have to go to the study.

3 Q. Well, 50 percent is less
4 than 80 percent, right?

5 A. I'm going to pull the study
6 out.

7 Q. Well, I'm asking you a
8 different question now. Is 50 percent
9 less than 80 percent?

10 A. I'm not going to answer the
11 question without -- it's comparing apples
12 and oranges.

13 Q. I'm just asking you a
14 numerical principle, is 50 percent less
15 than 80 percent?

16 MS. RELKIN: Objection,
17 Counsel. This is argumentive and
18 silly.

19 THE WITNESS: So Siegal is
20 "Probable Relationship Between
21 Opioid Abuse and Heroin Use"? So
22 that is Reference Number 96 in my
23 report. I'll just pull that out.

24 BY MR. HERMAN:

1 Q. That's okay. I'm not asking
2 you questions about that report right
3 now. Thank you.

4 A. Well, I would like to answer
5 the question.

6 Q. Well, I've got limited time,
7 and I'd like to ask my questions, please.

8 If you could look at Table 1
9 of the Compton study. And in your paper
10 you discuss --

11 A. I'm sorry. Table 1.

12 Q. Table 1 on Page 158. And in
13 your report, the Page 26, you discuss how
14 heroin use has increased from 138 percent
15 from 2002 to 2004?

16 A. Hold on a second. I need to
17 find the place in the report where that
18 is.

19 Q. It is on Page 26, middle of
20 the first paragraph.

21 A. Okay. "Among individuals
22 who use prescription opioids, heroin has
23 increased by 138 percent from 2002 to
24 2004 and 2011 to 2013 and the connection

1 is particularly strong among young
2 adults." That is the statement that I
3 make in the report.

4 Q. Okay. And if you turn back
5 to Table 1, Table 1 of the Compton study,
6 that shows that cocaine use had increased
7 by 87.3 percent.

8 A. I'm sorry, that's not
9 accurate. They're looking at the
10 percentage change in rates of heroin use
11 among the row defined user; is that
12 correct? So you said rates of cocaine
13 use have increased? I don't think that
14 is what that shows. Let me go to the --

15 MS. RELKIN: Table 1.

16 THE WITNESS: Table 1.

17 MS. RELKIN: Isn't that
18 this?

19 MS. WINNER: Excuse me,
20 Counsel.

21 MS. RELKIN: She's looking
22 at the wrong thing. If you want
23 her --

24 THE WITNESS: Are you

1 looking at Figure 1?

2 MS. RELKIN: He's referring
3 at Table 1. I'm trying to help.

4 MR. HERMAN: I'm looking at
5 Table 1 of the Compton report.

6 MS. RELKIN: She's looking
7 at Figure 1. Okay. Nothing
8 improper to try to have her look
9 at -- to be on the same page.

10 MR. HERMAN: We're on the
11 same page. Thank you for...

12 THE WITNESS: Okay. So
13 Table 1 is the annual average
14 rates of heroin use during the
15 previous year. According to the
16 substance use characteristic and
17 time period in the United States
18 from 2002 to 2013.

19 You made the statement that
20 they're describing changes in
21 cocaine use. But I believe these
22 are increases in heroin use among
23 the row defined users.

24 BY MR. HERMAN:

1 Q. Yes. Among individuals who
2 used cocaine in the past year, heroin had
3 increased 87.3 percent, right?

4 A. I think this goes back to
5 the topic that we were discussing earlier
6 in that heroin use has increased among a
7 whole broad swath of the population.
8 According to Table 1, the group in which
9 heroin use has increased the most --

10 Q. That's not my question,
11 right? I asked about --

12 MS. RELKIN: She's answering
13 your question.

14 MR. HERMAN: That is not an
15 answer to my question.

16 MS. RELKIN: You cut her
17 off. You cut her off.

18 MR. HERMAN: I mean, this
19 is -- I mean, she's got to answer
20 the questions that I'm asking.

21 MS. RELKIN: You don't know
22 where -- what the rest of her
23 sentence was going to be because
24 you cut her off.

1 MR. HERMAN: All right. I
2 mean, many of the answers today
3 have been very nonresponsive. But
4 please.

5 MS. RELKIN: Do you remember
6 where -- what the question was?

7 THE WITNESS: Can you ask
8 your question again?

9 BY MR. HERMAN:

10 Q. Among individuals who had
11 used cocaine in the past year, heroin use
12 increased 87.3 percent, right?

13 MS. RELKIN: From what time
14 period, Counsel?

15 MR. HERMAN: 2002 to 2004 to
16 2011 to 2013.

17 THE WITNESS: Again, that
18 one data point is in an entire
19 table. Heroin use increased among
20 binge users, marijuana users,
21 cocaine users, and nonmedical use
22 of other psychotherapeutic agents
23 in the previous year.

24 The group that it increased

1 the most was nonmedical use of
2 prescription opioids in the
3 previous year.

4 (Document marked for
5 identification as Exhibit
6 Keyes-12.)

7 BY MR. HERMAN:

8 Q. I'm handing you what's been
9 marked as Keyes Exhibit 12 which is the
10 Murray study referenced in your report
11 that you spoke about earlier.

12 I direct your attention to
13 Page 3. The full paragraph -- first full
14 paragraph where it says, "In the field of
15 substance abuse there are also theories
16 of common vulnerability, suggesting that
17 drug use is part of a general répétiteur
18 of risky behavior. This explanatory
19 model presumes that there are no
20 significant differences within the group
21 of illicit drug users and that the
22 selection of different drugs to consume
23 is largely a function of environmental
24 factors such as opportunity to use a

1 given drug." Do you see that?

2 A. Can you give me a minute to
3 just read it --

4 Q. Sure.

5 A. -- on my own.

6 Yes.

7 Q. Are you familiar with the
8 common vulnerability theory?

9 A. I am.

10 Q. Did you consider that in
11 assessing your causal analysis?

12 A. Yes.

13 Q. Okay. How so?

14 A. I, you know, there's
15 substantial decades of epidemiological
16 research on drug use that indicates that
17 there are individual characteristics,
18 including heritability, that predispose
19 some people to be more likely to be
20 addicted versus others.

21 However, supply,
22 availability, price, and the opportunity
23 to use determine not only the overall
24 population percentage, but what drugs

1 will be used by a particular person.

2 Q. And would you agree with me
3 that prior substance abuse is a -- is a
4 risk factor for heroin use?

5 MS. RELKIN: Objection to
6 form.

7 THE WITNESS: I think that
8 there are a whole range of risk
9 factors for drug use, abuse, and
10 addiction that range from
11 molecular to societal.

12 BY MR. HERMAN:

13 Q. Is prior substance abuse a
14 risk factor for nonmedical prescription
15 opioid use?

16 A. Can you be more specific of
17 what you mean by "prior substance abuse"?
18 Are you referring to a DSM category or?

19 Q. Well, I'm asking if someone
20 has a substance abuse issue, does that
21 put them more at risk for nonmedical use
22 of prescription opioids?

23 A. Do you mean -- what do you
24 mean by substance abuse issue?

1 Q. A diagnosed -- well, if
2 someone had previously used cocaine
3 regularly to get high, would they be more
4 at risk for nonmedical use of
5 prescription opioids?

6 MS. RELKIN: Objection to
7 form.

8 THE WITNESS: I would have
9 to see a particular study that
10 evaluated that issue.

11 BY MR. HERMAN:

12 Q. Okay. Can I ask you to turn
13 to Page 14 and to look at Table 6. It's
14 a table at the top of Page 14.

15 MS. RELKIN: Of Exhibit 12?

16 MR. HERMAN: Yes. Of the
17 Murray study.

18 THE WITNESS: So table -- it
19 gets cut off at the end of
20 Page 13, right? That --

21 BY MR. HERMAN:

22 Q. Yeah. And I think it's --
23 the back is on page --

24 A. Okay. I just want to make

1 sure I read the title.

2 Q. Okay. And this table shows
3 somewhere between 69.7 percent and
4 73.9 percent of people who were
5 nonmedical users of prescription opioids
6 previously abused some other illicit
7 substance, right?

8 A. I'm sorry. I'll just need
9 to take a minute.

10 Q. I'll direct your attention
11 to the -- the data that's the third row
12 of numbers down in the table.

13 A. Okay. Okay. "So percentage
14 distribution of past year nonmedical pain
15 reliever use among individuals 12 to 49
16 at risk for initiation of nonmedical pain
17 and were used by prior illicit drug use
18 status..."

19 So this looks -- this
20 stratifies the data, the data on past
21 year nonmedical pain reliever use among
22 people in a specific age by prior heroin
23 use status. Among individuals who did
24 not use heroin prior to NMPR, which

1 stands for nonmedical pain reliever?

2 Let's just double-check that.

3 Nonmedical prescription pain
4 reliever.

5 So among those who did not
6 use heroin prior to their nonmedical
7 prescription pain reliever use, in 2002
8 to 2004, 73.9 percent had used another
9 illicit drug prior to their nonmedical
10 prescription opioid use.

11 And the overall, from 2002
12 to 2011, 71.5 -- 71.8 percent had used
13 another -- one thing I would like to
14 actually clarify though. Do you see
15 what's in Footnote 2? So other illicit
16 drugs includes marijuana, hashish,
17 cocaine including crack, hallucinogens
18 and inhalents.

19 Q. Okay. Thank you for that
20 clarification. Would -- would you
21 interpret this data as showing that
22 people who are drug users seek out
23 prescription opioids for nonmedical use?

24 MS. RELKIN: Objection to

1 form.

2 THE WITNESS: That's not --
3 that is not how I would interpret
4 these data. I think that there is
5 evidence epidemiologically that
6 there is a -- that individuals --
7 it's not a causal analysis of the
8 other illicit drug use, the
9 percentage that -- that's
10 described here, in terms of the
11 risk of nonmedical prescription
12 pain reliever use.

13 BY MR. HERMAN:

14 Q. The percentages of what --

15 A. So you're asking me if I
16 would interpret this data as saying that
17 people who are drug users seek out
18 prescription opioids. And I don't see
19 that statement supported in this work.
20 That's a different question than what is
21 asked here.

22 What is asked here is just
23 the percentage of people who used another
24 illicit drug for their nonmedical

1 prescription opioid use. There's no
2 comparison group. There's no assessment
3 of drug seeking.

4 Q. There's just a percentage of
5 what they used first, that's the issue?

6 A. That is other illicit drug
7 use prior to nonmedical prescription pain
8 reliever use. And you're asking whether
9 that's evidence that people who are drug
10 users seek out prescription opioids. And
11 I don't -- that's not evaluated in this
12 table.

13 Q. Would you agree that other
14 illicit drug use is a risk factor for
15 nonmedical prescription opioid use?

16 MS. RELKIN: Objection to
17 form.

18 THE WITNESS: Is there a
19 particular paper that you want me
20 to evaluate?

21 BY MR. HERMAN:

22 Q. Well, have you evaluated
23 that?

24 A. As I have said throughout

1 this report, there are a number of
2 studies that have examined things like
3 prior drug use as an -- in terms of
4 associations with prescription opioid
5 use. Regardless of prior drug use, the
6 supply of prescription opioids increased
7 the use of prescription opioids and the
8 diversion of prescription opioids in the
9 population. So the fact that there are
10 individual level vulnerabilities that
11 predict who uses and who doesn't, doesn't
12 explain the overall increase in the
13 supply that occurred rapidly. We didn't
14 have that many more individuals in a very
15 short period of time who had high
16 propensity to be addicted to drugs. The
17 supply is the thing that changed.

18 Q. Could the individual level
19 risk factors predict who goes on to use
20 heroin from prescription drugs?

21 MS. RELKIN: Objection to
22 form.

23 THE WITNESS: I'm sorry.

24 What -- could you rephrase the

1 question?

2 BY MR. HERMAN:

3 Q. Let me -- let me ask you
4 differently maybe.

5 If someone uses cocaine
6 regularly, then uses nonmedical
7 prescription opioids and then uses
8 heroin, would you say that the nonmedical
9 prescription opioid use caused the heroin
10 use?

11 MS. RELKIN: Objection to
12 form.

13 THE WITNESS: So what we do
14 epidemiologically is not evaluate
15 individual cases. What we look at
16 is population level patterns. And
17 what the population level patterns
18 indicate is that even if you
19 control for a prior drug use,
20 there is an increase in the risk
21 of transition to heroin use given
22 the use of prescription opioids at
23 a population level.

24 BY MR. HERMAN:

1 Q. A number of the studies that
2 you rely on though just looked at what
3 opioid was the opioid of first use,
4 right?

5 A. I looked at a wide range of
6 studies. Again, I built an evidence base
7 across studies of different design,
8 population type --

9 Q. But you would agree with me
10 for example, that Cicero just looked at
11 the first opioid of use, right?

12 A. Which Cicero paper?

13 Q. Well, the only one that you
14 cited in your report.

15 A. I believe I cited a number
16 of Cicero papers. I could be --

17 Q. I believe -- well, I believe
18 you only cited one --

19 A. He might have been co-author
20 on other papers that I cited.

21 Q. Oh. Well, that -- that may
22 be fair. But the one we looked at
23 earlier, you would agree that it looked
24 at what was the opioid of first use.

1 A. Let me just pull out the
2 paper. This is the "Changing Face of
3 Heroin Use."

4 Okay. So this is Cicero
5 2014. "Survey of Key Informants
6 Patients." And so your question is?

7 Q. Well, the Cicero report that
8 you -- it looked at what was opioid of
9 first use, right?

10 A. So the Cicero paper was one
11 of a number of papers that I cited in
12 that section as building the evidence
13 base for the causal relationship.

14 This particular study used a
15 patient -- not a patient population. A
16 population of participants that met
17 DSM-IV criteria for substance abuse with
18 the primary drug of an opioid,
19 prescription drug, or heroin and asked
20 them the decade of first use for each of
21 those drugs, yes.

22 Q. In your report you state
23 that numerous factors predict transition
24 from prescription opioid use to heroin

1 use including individual level and
2 community level characteristics, right?

3 A. Can you point to the section
4 of the report where that's stated?

5 Q. Yes. Page 27, around the
6 middle of the first paragraph.

7 A. Numerous factors predict
8 transition from prescription opioids
9 to... including individual level and
10 community level characteristics.

11 That is what is written.

12 Q. What do you mean by
13 transition?

14 A. In that sentence what I'm
15 specifically referring to is the increase
16 in risk for heroin use, given first use
17 of prescription opioids.

18 Q. You say numerous factors.
19 So what are the numerous factors that
20 predict transition from prescription
21 opioid use to heroin use?

22 A. So I would point to a number
23 of studies that have examined individual
24 level factors. I would like to pull up

1 Cerdá. Let me just see what number it
2 is.

3 I'm going to need to find
4 it. If you know what number Cerdá, is I
5 can pull it up.

6 Q. Well, can you think of any
7 of the numerous factors that --

8 A. I just want to be accurate
9 in my answer. And so I would like to
10 pull up the paper that looked at
11 individual level factors.

12 Q. You don't know what you
13 meant when you wrote "numerous factors
14 predict transition"?

15 MS. RELKIN: Objection to
16 form.

17 THE WITNESS: I know what I
18 meant. I want to look up the
19 paper.

20 BY MR. HERMAN:

21 Q. Can you just tell me what
22 you meant at the time?

23 A. 88.

24 Q. All right. Why don't we --

1 okay.

2 A. So the characteristics that
3 were evaluated in the Cerdá paper
4 included sex, age, race, ethnicity, age
5 of initiation of nonmedical use
6 prescription opioids, prior use of drugs,
7 alcohol, household income, residence, and
8 year.

9 Q. Okay. Thank you.

10 A. And I can tell you what each
11 of them are associated with.

12 Q. No, that's okay. I was just
13 looking at the factors that you were
14 thinking of.

15 You've written about
16 availability proneness theory, correct?

17 A. I wouldn't call it --

18 MS. RELKIN: Objection to
19 form.

20 THE WITNESS: --

21 availability proneness theory.

22 But I've -- it's most often
23 referred to in the literature as
24 availability theory.

1 BY MR. HERMAN:

2 Q. Have you written a paper
3 that used the terminology of "available
4 proneness theory"?

5 A. Different terms are used in
6 the literature. What's most often used
7 is availability theory. But I've heard
8 it referred to as availability proneness
9 as well.

10 Q. And --

11 A. I wrote about it in this
12 report as availability theory.

13 Q. Okay. And in the paper that
14 I'm thinking of, you defined it as -- or
15 the paper -- you were one of the
16 authors -- defined it as, "Availability
17 proneness theory of drug use posits that
18 drug use occurs when individuals who are
19 prone to using are exposed to high
20 availability."

21 A. I would need to see the
22 paper.

23 Q. Okay. You don't -- you
24 don't recall that?

1 A. One sentence in a paper
2 needs to be placed into context. And so
3 to respond to the statement about what I
4 meant by that statement, I need to see
5 the context in which it was written.

6 Q. Well, do you disagree with
7 that definition of availability
8 proneness?

9 A. I'd have to see the paper to
10 see what the statement was referring to
11 specifically.

12 MS. RELKIN: Counsel, can
13 you please provide her with the
14 paper, so she can answer the
15 question.

16 MR. HERMAN: I'm asking her
17 if she disagrees with that
18 definition. If she can't answer,
19 that's fine.

20 BY MR. HERMAN:

21 Q. You would agree that in many
22 of the studies that you discussed a
23 frequent reason given for using heroin is
24 price and availability, correct?

1 A. So --

2 MS. RELKIN: Objection to
3 form.

4 THE WITNESS: -- there are
5 some studies that looked at that
6 specific issue.

7 Okay. So this is I think
8 Reference 87. Is that Compton?
9 That's Compton. In my statement I
10 write, reasons cited for the
11 transition to heroin use given
12 prescription opioids use based on
13 the research cited above is most
14 often cost and convenience
15 reasons. Prescription opioids are
16 more expensive to obtain illegally
17 than heroin and difficult to get
18 in some geographic areas.

19 BY MR. HERMAN:

20 Q. Isn't one alternative
21 hypothesis that some people who engage in
22 nonmedical use of prescription opioids
23 switched to other opiates when those
24 became cheaper or more readily available?

1 MS. RELKIN: Objection to
2 form.

3 THE WITNESS: Isn't one
4 alternative --

5 BY MR. HERMAN:

6 Q. I'm not --

7 A. So I don't see what -- okay.
8 So I'm saying here, reasons cited for the
9 transition to heroin use given
10 prescription opioids use based on the
11 research cited above is most often cost
12 and convenience.

13 And your question is, is it
14 an alternative hypothesis that some
15 people who engage in nonmedical use of
16 prescription opioids switched to other
17 opioids when those became cheaper or -- I
18 mean, I cite cost and convenience. I'm
19 wondering what -- how -- what's the
20 alternative that you're proposing.

21 Q. Okay. So -- okay. So maybe
22 we are in agreement then.

23 A. I would disagree with the
24 statement that the transition to heroin

1 use is restricted to nonmedical users of
2 prescription opioids.

3 Q. You discuss prescription
4 opioids being causally related to heroin
5 use. Did you look at any particular type
6 of prescription opioid?

7 A. The available literature
8 that I cite in this section looks at a
9 wide range of opioid products.

10 Q. What's your best support in
11 the data for concluding that the use of
12 hydrocodone, acetaminophen combination
13 products specifically, cause an increase
14 in heroin use?

15 MS. RELKIN: Objection to
16 form.

17 THE WITNESS: I'm sorry.
18 Where in the -- where in the
19 witness statement are you?

20 BY MR. HERMAN:

21 Q. I'm not referring to your
22 report. I'm asking you a question. At
23 trial are you only going to be able to
24 read from your report?

1 A. I would like to -- well, I
2 wrote the report. And so if you're
3 asking me a specific question, I want to
4 make sure I have all the data available
5 because there's over 200 references in
6 it.

7 Q. Do you recall any data that
8 supports the conclusion that the use of
9 hydrocodone/acetaminophen combination
10 products specifically cause an increase
11 in heroin use?

12 A. Is there a specific study
13 that you're referring to? I mean, the
14 studies that I cite in this report cite a
15 lot -- a broad range of products.

16 Q. Okay.

17 A. I mean, OxyContin is
18 specifically mentioned.

19 If there's a specific study
20 that I can look at for you, I can give
21 you an answer.

22 Q. That's okay. She can't...

23 A. My take on the
24 epidemiological literature is that

1 there's a broad range of products that
2 are mentioned in these studies.

3 THE WITNESS: Can we take a
4 break?

5 MR. HERMAN: Sure.

6 MS. RELKIN: Yeah.

7 THE VIDEOGRAPHER: All
8 right. Remove your microphones.
9 The time is 2:54 p.m. Off the
10 record.

11 (Short break.)

12 THE VIDEOGRAPHER: All
13 right. We are back on the record.
14 The time is 3:10 p.m.

15 MR. HERMAN: Before we get
16 started again, I just want to
17 state on the record that we're
18 going to reserve our right to seek
19 more time or strike the witness.
20 Our ability to effectively examine
21 this witness has been prejudiced
22 today by her repeating back
23 questions, not directly answering
24 questions. Special Master Cohen

1 ruled last week that we're
2 entitled to straightforward
3 answers to our question. We
4 certainly haven't received those
5 today.

6 And so for those reasons,
7 among others, in the evasiveness
8 of the answers and taking up time,
9 we are going to reserve our right
10 to seek more time or strike the
11 witness.

12 MS. RELKIN: We vigorously
13 oppose your characterization. The
14 witness has been forthright. Some
15 of your questions are quite
16 challenging to answer. And she's
17 been responsive.

18 BY MR. HERMAN:

19 Q. Professor Keyes, you've said
20 a couple times today that prior
21 prescription opioids use is a risk factor
22 for later heroin use, right?

23 A. I've said that the
24 epidemiological literature indicates that

1 prescription opioid use is a risk factor
2 for heroin use.

3 Q. Can you identify any other
4 risk factors for heroin use?

5 A. There are a number of
6 different risk factors for heroin use.
7 Would you like me to -- to cite a
8 specific study or just based on my
9 general background knowledge, or...

10 Q. Well, I'd like you to just
11 tell me what the risk factors for heroin
12 use are.

13 A. I mean, I -- so there is a
14 number of different risk factors for all
15 kinds of illicit and licit drug use. For
16 heroin use in particular, there's
17 demographic risk factors, for example
18 male sex is something I cite in the
19 report as a risk factor for heroin use.
20 There's other demographic risk factors.
21 Behavioral risk factors. Supply risk
22 factors. Environmental risk factors.

23 Usually through a kind of
24 macro social lens we examine risk factors

1 for substance use from a number of
2 different levels, from both molecular,
3 cellular, genetic, up through societal
4 level.

5 Q. Professor Keyes, you opine
6 in your report that since approximately
7 2013, prescription opioid use is also
8 causally related to the increase in
9 synthetic opioid morbidity and mortality
10 since prescription opioids precede the
11 transition to heroin, including heroin
12 contamination with fentanyl, right?

13 A. So I'm -- I think you're
14 specifically referring to Page 3 in which
15 I state "because the heroin supply has
16 been contaminated with high potency
17 synthetic opioids, for example fentanyl.
18 Since approximately 2013 prescription
19 opioid use is also causally related to
20 the increase in synthetic morbidity and
21 mortality."

22 Q. Okay. And is the support
23 for that conclusion also contained in
24 Section B.7 of your report?

1 I direct you to the last
2 paragraph on Page 27, the last paragraph
3 of Section B.7 on Page 27.

4 A. So the citations that I use
5 in that paragraph are, one, that we know
6 that fentanyl is more potent than heroin
7 and other synthetic opioids as well.
8 Fentanyl is an example.

9 And also that fentanyl and
10 other high potency opioids have been
11 adulterating the supply of heroin and
12 illicitly manufactured prescription
13 opioids.

14 So -- so because the heroin
15 supply has been adulterated with high
16 potency synthetic opioids, and because
17 I've established that prescription opioid
18 use is a cause of heroin use, then
19 prescription opioid use then is a cause
20 of fentanyl use.

21 Q. Okay. And I just want to
22 make sure I understand sort of your
23 analysis.

24 First, in Section B.7 you

1 discuss literature that you believe shows
2 there is a causal relationship between
3 prescription opioid use and heroin use,
4 right?

5 A. "You discuss literature you
6 believe shows there is a causal
7 relationship between prescription opioids
8 use and heroin use."

9 Yes, that's correct.

10 Q. Okay. And then you note
11 that available evidence indicates that
12 fentanyl and other high potent opioids
13 have been adulterating the supply of both
14 heroin and illicit -- illicitly
15 manufactured prescription opioids, right?

16 A. That's correct.

17 Q. What do you mean when you
18 say adulterated?

19 A. I'm -- I'm not sure if I
20 have that in the definitions section.

21 Typically in the literature,
22 the term "adulterated" means that it is
23 mixed together with.

24 Q. Okay. And the third step in

1 your analysis is you state that "due to
2 the adulteration, people who intend to
3 obtain heroin or illicitly manufactured
4 opioids may unintentionally expose
5 themselves to fentanyl," right?

6 A. Can I just find where that
7 statement is to make sure that it's not
8 qualified with something I want to
9 qualify it with?

10 Q. Yes. It is towards the
11 middle of the last paragraph on Page 27.

12 A. The -- the middle of the
13 last paragraph before B.8?

14 Q. Yes.

15 A. Okay. Excuse me.

16 Given the evidence of
17 prescription opioid use is causally
18 related to heroin use -- okay. I see
19 what you're saying.

20 Indeed individuals...
21 potentially exposed to fentanyl and risk
22 of overdose and death.

23 Yes, that is what I wrote.

24 Q. Okay. So that's the third

1 step in your analysis, right?

2 A. I'm sorry, can you repeat
3 Steps 1 and 2?

4 Step 1 is prescription
5 opioid use is causally related to heroin
6 use.

7 Step 2 is heroin use is
8 adulterated with high potency synthetic
9 opioids.

10 Step 3 is individuals who
11 use heroin may be potentially exposed to
12 high potency synthetic opioids.

13 Q. Yes. And -- and the last
14 step is you conclude that because some of
15 the studies show that available estimates
16 indicate that 80 percent of individuals
17 who use heroin begin their opioid use
18 using trajectories with prescription
19 opioids, you estimate that approximately
20 80 percent of fentanyl-involved deaths
21 are attributable to prescription opioids?

22 A. Yes.

23 Q. Okay. And you refer to the
24 80 percent of fentanyl-involved deaths

1 that you attribute to prescription
2 opioids as an estimate, right?

3 A. Yes, it is an estimate.

4 Q. What have you done to verify
5 your estimate that approximately
6 80 percent of fentanyl-involved deaths
7 are attributable to prescription opioid
8 use?

9 A. I think what I have done to
10 evaluate that percentage is outlined in
11 the methodology that I used to develop
12 this report.

13 What I did, I reviewed the
14 literature on the association between
15 prescription opioid use and heroin use.
16 And I also reviewed the literature on
17 heroin use and heroin-involved fentanyl
18 deaths that are in the report.

19 Q. Did you review any articles
20 that discuss a causal relationship
21 between prescription opioids and
22 fentanyl?

23 A. So what I reviewed in the
24 report is the relationship between

1 prescription opioid use and heroin use.
2 And there is also epidemiological
3 evidence that I have cited in this report
4 that indicates that in the last three
5 years, heroin use has been adulterated
6 with high potency synthetic opioids.
7 Therefore, if individuals are using
8 heroin, they are potentially exposed to
9 fentanyl.

10 Q. Did you review any articles
11 that state that 80 percent of
12 fentanyl-involved deaths are attributable
13 to prescription opioids?

14 A. Did you review any articles
15 that state that 80 percent of fentanyl --
16 I'm sorry. This is incorrect.

17 Q. Let me repeat the question.
18 Did you review any articles that state
19 that 80 percent of fentanyl-involved
20 deaths are attributable to prescription
21 opioids?

22 A. So that estimate is based on
23 the literature review that I did. That
24 is based on the literature involving

1 prescription opioids use prior to heroin
2 use and the adulteration of the heroin
3 supplied with high potency, synthetic
4 opioids. So that is the estimate that I
5 derive from my expert opinion.

6 Q. But no article that you
7 reviewed actually states that 80 percent
8 of fentanyl-involved deaths are
9 attributable to prescription opioids,
10 right?

11 A. The available literature, I
12 think, is robust in the percentage of
13 heroin users that begin with prescription
14 opioids, especially in recent decades.

15 And in the last three years,
16 there has been adulteration of the heroin
17 supply with fentanyl. So I think it is a
18 reasonable conclusion to draw that
19 heroin-involved, fentanyl-involved deaths
20 that began with -- that are causally
21 related to prescription opioids would be
22 included in the assessment of the
23 literature that I did.

24 Q. Okay. But my specific

1 question was, did any article that you
2 reviewed state that 80 percent of
3 fentanyl-involved deaths are attributable
4 to prescription opioids?

5 A. That statement that I made
6 was based on the literature that I
7 reviewed, about the proportion of heroin
8 users that begin with prescription
9 opioids. Given that in the last three
10 years, the heroin supply has been
11 adulterated with fentanyl, it has caused
12 an increase in overdose deaths.

13 The conclusion that I drew
14 from my review of the literature and my
15 expertise in epidemiology is that I
16 estimate that 80 percent of the fentanyl
17 deaths are due to prescription opioids.

18 Q. But that's an estimate,
19 right?

20 A. Everything in epidemiology
21 is estimated from data.

22 Q. Have you heard of fentanyl
23 being used with non-opioid drugs?

24 A. Have I heard of it? So

1 there's literature cited in here about
2 fentanyl being used in other drugs.

3 Q. Cocaine?

4 A. I believe there is
5 literature cited in here about
6 fentanyl-adulterated cocaine.

7 Q. Marijuana?

8 A. I would have to go to the
9 specific cite to know the percentage for
10 marijuana. I don't know that it is -- I
11 don't know off the top of my head what
12 the specifics with regard to marijuana
13 and fentanyl are. But I can find the
14 citation.

15 Q. Methamphetamine?

16 A. Again, I would -- I would
17 have to look for the citation. I believe
18 it's Rudd from the CDC. So I can --

19 Q. Well, I'm just asking, have
20 you heard of fentanyl being used with
21 methamphetamine?

22 MS. RELKIN: Objection to
23 form.

24 BY MR. HERMAN:

1 Q. I'm not asking you for a
2 percentage. Are you aware of data that
3 shows that fentanyl --

4 A. I will -- I know that the
5 CDC has evaluated decedents that have
6 toxicological reports. So we can look at
7 those data if that would be --

8 Q. Well, sitting here today, do
9 you recall seeing data that shows
10 fentanyl --

11 A. I don't see how that's
12 germane to the issue of the proportion of
13 fentanyl deaths that are due to
14 prescription opioids, because the
15 specific figure that I cite is about
16 heroin users. And so the fact that there
17 may be individuals who also use fentanyl
18 in other drugs and die from it, doesn't
19 change the estimate of 80 percent of
20 heroin users started with prescription
21 opioids.

22 So, yes, there are other
23 people who are also dying from fentanyl.

24 Q. You're opining about the

1 percentage of fentanyl deaths that
2 involve heroin, correct?

3 A. The specific statement that
4 I make -- let's see.

5 Q. You estimate that
6 approximately 80 percent of fentanyl
7 involved deaths are attributable to
8 prescription opioid use, right?

9 A. So can you point me to the
10 specific page number?

11 Q. Well --

12 A. 27?

13 Q. Yes. The last sentence.

14 A. So it's 80 percent of those
15 who are using heroin.

16 Q. So -- but what you wrote is
17 that 80 percent --

18 A. That's what I wrote. "In
19 terms of the magnitude and scope of the
20 relationship, given that available
21 estimates indicate that 80 percent of
22 individuals who use heroin" -- I'm
23 specifically referring to heroin users.
24 So other people also use fentanyl and die

1 from it.

2 Q. And if, for example,
3 50 percent of fentanyl-involved deaths
4 are attributable to cocaine mixed with
5 fentanyl, your estimate would be
6 incorrect?

7 A. No, it would not be
8 incorrect. It would be a different
9 research question entirely, right?
10 Again, I'm talking about among heroin
11 users, approximately 80 percent, based on
12 the studies that I cite, began their
13 opioid using careers with prescription
14 opioids.

15 So to the extent that heroin
16 use is adulterated with fentanyl, I would
17 estimate that approximately 80 percent of
18 heroin and fentanyl-related deaths are
19 due to prescription opioids. There might
20 be more deaths due to fentanyl that are
21 outside that particular estimate. But
22 that doesn't change this estimate in the
23 report.

24 Q. That's not what you wrote

1 though, right? You wrote, "I estimate
2 that approximately 80 percent of
3 fentanyl-involved deaths are attributable
4 to prescription opioids."

5 A. I think it's clear from the
6 first part of the sentence that I was
7 referring to 80 percent of the
8 individuals who use heroin. So the
9 second part of the sentence has to be
10 read with the first part of the sentence.

11 Q. Okay. So you're saying that
12 80 percent of heroin users -- I guess I'm
13 not following the linkage to fentanyl
14 deaths. What percentage of
15 fentanyl-related deaths are you
16 estimating are due to prescription drugs?

17 A. That's a different question
18 than the one that I outlined in this
19 paragraph. So we would need to take all
20 of the fentanyl deaths and understand all
21 of the toxicology reports that are
22 involved in all the fentanyl deaths in
23 order to come up with that number, which
24 I can do.

1 Q. So --

2 A. But that's not what this
3 sentence is referring to.

4 Q. I want to make sure I
5 understand, because I'm not sure I do.

6 What are you -- what do you
7 believe you're saying in this sentence?

8 A. I believe what I'm saying in
9 this sentence is that the epidemiological
10 evidence has indicated that approximately
11 80 percent of heroin users begin their
12 opioid using careers with prescription
13 opioids use. To the extent that heroin
14 use in the last three years has been
15 adulterated with fentanyl, approximately
16 80 percent of those deaths would be due
17 to prescription opioids.

18 Q. And what deaths are we
19 talking about?

20 A. The heroin deaths that are
21 adulterated with the fentanyl supply.

22 Q. Okay. Have you submitted
23 your estimate to any publications?

24 A. I have not.

1 Q. Do you have to do additional
2 work to verify your estimation before
3 submitting it for publication?

4 MS. RELKIN: Objection to
5 form. Assumes facts not in
6 evidence.

7 THE WITNESS: I'm sorry.
8 Can you ask the question again.

9 BY MR. HERMAN:

10 Q. Would you have to do
11 additional work to verify your estimate
12 before submitting it for publication?

13 A. I would be perfectly happy
14 to submit this for peer-reviewed
15 publication.

16 Q. You'd accept this estimate
17 for publication in the journal of drug
18 and alcohol dependence where you're an
19 associate editor?

20 A. I haven't submitted it for
21 publication, so I don't want to speculate
22 on where I would submit it for
23 publication. But I am an associate
24 editor of Drug and Alcohol Dependence.

1 Q. Okay. And --

2 A. That's one among many
3 journals that I could publish the
4 literature review that I've done here.

5 Q. You could publish this
6 80 percent fentanyl estimate in a
7 journal?

8 A. I haven't published it. If
9 I were to write this for publication, I
10 would need a research question. You
11 know, that one number is not sufficient
12 for a peer-reviewed publication. But in
13 the context of a publication, I would
14 have no problem submitting this for peer
15 review.

16 Q. Did you look at data at
17 any -- well, strike that.

18 Did you look at any
19 statistics from Cuyahoga County to see if
20 the data supported your estimate?

21 MS. RELKIN: Objection to
22 form.

23 THE WITNESS: Which
24 statistics in particular are you

1 referring to?

2 BY MR. HERMAN:

3 Q. Well, your estimate that
4 approximately 80 percent of
5 fentanyl-involved deaths are attributable
6 to prescription opioid use?

7 A. So I think this gets back to
8 an earlier question about the Cuyahoga
9 County data. In that as far as I'm
10 aware, there is no publication that has
11 listed the proportion of heroin users in
12 Cuyahoga who began their opioid using
13 careers with -- with prescription
14 opioids. However, given the diversity of
15 studies that I've cited in that section
16 with diverse populations, I -- I think
17 the generalizability of the estimate is
18 more sound across geographic location.

19 Q. Did you ask anyone if there
20 was any data available from Cuyahoga
21 County that would allow you to attempt to
22 verify your estimate?

23 A. If there's any data on -- on
24 the number of heroin users in Cuyahoga

1 County? Is that the question? What
2 data -- what data?

3 Q. That approximately
4 80 percent of fentanyl-involved deaths
5 are attributable to prescription opioid
6 use.

7 A. And -- and so the question
8 is, did I ask anyone -- as -- as I said,
9 as far as I know, there's no published
10 studies on the opioid use history of
11 heroin users in the county. I've cited a
12 number of -- of population sizes about
13 Cuyahoga and Summit County in the report.

14 Q. Did you ask if there was any
15 data available to attempt to verify your
16 estimate?

17 MS. RELKIN: Objection to
18 form. Asked and answered.

19 THE WITNESS: I have -- I
20 have outlined what my criteria
21 were in the report. I -- I don't
22 have any additional information on
23 that topic.

24 MR. HERMAN: All right. I'm

1 going to go off the record for a
2 second.

3 THE VIDEOGRAPHER: Okay.
4 The time is 3:30 p.m. Off the
5 record.

6 (Brief pause.)

7 THE VIDEOGRAPHER: Okay.
8 The time is 3:31 p.m. Back on the
9 record.

10 - - -

11 EXAMINATION

12 - - -

13 BY MS. WINNER:

14 Q. Good afternoon, Professor
15 Keyes. My name is Sonya Winner. I
16 represent McKesson in this case, and I'm
17 here to ask you some additional
18 questions. Hopefully not repeating
19 anything.

20 Before we get started, I --
21 I know you're not feeling very well
22 today. And I just want to make sure
23 that -- it's already been a long day, are
24 you feeling up to continuing for the --

1 A. I'm feeling up to
2 continuing, thank you.

3 Q. Okay. And are you on any --
4 any cold medications or anything that you
5 are concerned might have been interfering
6 with your ability to testify today?

7 MS. RELKIN: Objection.

8 THE WITNESS: I'm -- I am
9 not concerned with my ability to
10 testify today.

11 BY MS. WINNER:

12 Q. Okay. A question that I
13 like to ask experts and I don't think
14 you've been asked today is whether you,
15 as you're sitting here today, have any
16 corrections that you'd like to make to
17 your report.

18 Is there anything that you
19 discovered in your recent review that
20 you'd want to change or correct or
21 anything like that?

22 A. I noticed a few typos when I
23 was reading over that were -- I would
24 want to correct.

1 Other than those typos, you
2 know, the -- the literature is -- is
3 quite rapid in this area. So I know that
4 there's two papers that we subsequently
5 disclosed and I would evaluate those to
6 see whether they should be included. And
7 then I would -- you know, any literature
8 that's come out since then I would update
9 my literature search.

10 Q. Is there any -- are there
11 any other corrections that you would make
12 as you sit here today?

13 A. None that come to mind.

14 Q. Now, one of the -- the major
15 things that you do in your everyday work
16 is to prepare papers for publication in
17 peer-reviewed journals, correct?

18 A. That is one thing that we
19 do, but it's --

20 Q. One of many things?

21 A. One of many things that we
22 do is write papers for publication.

23 Q. Okay. Now, when you're
24 doing that, if you're presenting an

1 analysis that relies on data or other
2 information, am I correct that you -- you
3 carefully source that information and
4 identify your sources in the paper,
5 correct?

6 A. I'm sorry, can -- I -- I
7 just need to read the question.

8 When I'm presenting an
9 analysis that relies on data or other
10 information, I carefully source that
11 information.

12 Can you give me an example?
13 I'm citing the literature. I -- I looked
14 at the literature that I'm citing.

15 Q. If you have a statement for
16 example, that 14 percent of the
17 population has a certain characteristic,
18 you would want to include some kind of
19 citation for that, correct?

20 MS. RELKIN: Objection to
21 form. Overbroad.

22 THE WITNESS: We cite
23 literature in our peer-reviewed
24 publications that we feel at the

1 time are available evidence
2 regarding that -- those statements
3 that we make if they are relying
4 on prior literature.

5 BY MS. WINNER:

6 Q. And you -- before you cite
7 something, you review the source that
8 you're citing to make sure you feel
9 comfortable in citing it, correct?

10 A. Every attempt is made -- you
11 know, I'm a -- I have 250 publications.
12 I'm a co-author on many. I am a first
13 author on many.

14 You know, I -- I don't
15 look -- I don't personally look at every
16 single citation that is in every single
17 one of those 250 papers. But I do, to
18 the best of my ability, when I'm reading
19 a paper, I read it with the citation list
20 and do my best to make sure that things
21 are cited, again, at the time.

22 Things change, science
23 progresses. So what was an appropriate
24 citation at one point could become an

1 inappropriate citation at another point.

2 But I do --

3 Q. Because --

4 A. -- I do my very best as a
5 scientist.

6 Q. Now, when you were doing the
7 work -- your work in preparing your
8 report in this case, did you feel that
9 that work was entitled to the same level
10 of rigor and care that you would have put
11 into preparing a peer-reviewed journal
12 article?

13 A. I mean again, I had some
14 typos. But aside from the typos, I -- I
15 used the same methodology that I use when
16 I'm preparing a literature review.

17 Q. And were you equally careful
18 in the work you did?

19 A. I -- I am always the same
20 level of carefulness in my work. I
21 applied the same level of rigor in all my
22 work.

23 Q. What -- a couple times
24 earlier today you used the word

1 heterogenous. I don' know, I'm not sure
2 I'm pronouncing that --

3 A. Heterogenous.

4 Q. Heterogenous. Missing a
5 vowel.

6 Can you define for us what
7 that term means to you as an
8 epidemiologist?

9 A. When we use the term
10 "heterogenous" in epidemiology, we mean
11 literally different.

12 So it's used in many
13 different ways -- many heterogenous ways
14 I would say. And just refers to
15 differences.

16 Q. And it's -- is the opposite
17 of heterogenous, homogenous?

18 A. That's correct.

19 Q. Now, I'd like to ask you
20 about Section C of your report which I
21 think starts on Page 30. Are you with
22 me?

23 A. Mm-hmm.

24 Q. And in this section you say,

1 and I direct your attention to the second
2 paragraph of Section C where you say that
3 you'll focus on the evidence for a
4 three-point abatement plan.

5 Do you see that?

6 A. I say, "These policies" --
7 "programs and policies will not be
8 reviewed in my report" -- referring to
9 prescription drug monitoring programs and
10 other drug disposal facilities,
11 et cetera. "Rather, I will focus on the
12 evidence for a three-point abatement
13 plan."

14 Q. Okay.

15 A. So I just want to be clear
16 that that was -- and as I state, other
17 programs and policies have also been
18 implemented. My focus on these aspects
19 is intended to be illustrative, not
20 exhaustive. So I'm not proposing
21 intending that these three policies and
22 programs are exhaustive of everything
23 that should be done.

24 Q. No, completely understood.

1 My question is, first of all, very basic.
2 What do you mean by the word "abatement"
3 there?

4 A. What I was referring to with
5 the word "abatement" in that sentence was
6 efforts to reduce opioid use disorder and
7 overdose, morbidity, and mortality.

8 Q. And you focus in your report
9 on the three points, medication-assisted
10 treatment, MAT. Is that called MAT
11 sometimes or --

12 A. Sometimes it's called MAT.

13 Q. What do you call it?

14 A. I call it MAT usually.

15 Q. Okay. Medication-assisted
16 treatment, harm reduction through
17 naloxone availability, and synthetic
18 opioid testing and warning systems.
19 Those are the three you focus on,
20 correct?

21 A. Those are three that I focus
22 on. That's correct.

23 Q. Why did you select those
24 three specific interventions to discuss

1 in your report?

2 A. So as I mentioned in the
3 report, there are other programs and
4 policies that counties have -- have
5 developed, have considered. I think
6 there's different levels of evidence for
7 them. I felt that these three in
8 particular had a solid evidence base
9 for -- again, not exhaustive. But these
10 three are three really solid ways to
11 reduce opioid use disorder and morbidity
12 and mortality that have evidence
13 associated with them.

14 Q. Did you think that these
15 three were the ones that had the best
16 evidence bases that you were aware of?

17 A. I would --

18 MS. RELKIN: Objection to
19 form.

20 You can answer.

21 THE WITNESS: I -- I was not
22 asked to evaluate the best
23 policies and programs. I was
24 asked to -- my approach to this

1 report was to outline the evidence
2 for three solid programs that had
3 a strong evidence base.

4 BY MS. WINNER:

5 Q. My question is --

6 A. I'm not sure what the best
7 means. Can you --

8 Q. Well, the best evidence I
9 think, is actually, what I asked you.
10 Were those the ones that you thought had
11 the best evidence?

12 A. Not necessarily. I think
13 there's a combination of factors that one
14 needs to use and that we use in public
15 health when choosing what programs and
16 policies to highlight in these types of
17 contexts. One is the level of evidence.
18 Another is the anticipated impact.

19 So I think, you know, among
20 other reasons that one would focus on
21 particular policies, I thought these
22 three had both a solid evidence base and,
23 specific to the counties, there was
24 enough information to suggest that there

1 would be an impact on the epidemic.

2 Q. Were there any other reasons
3 other than the ones you just described
4 why you selected these three?

5 A. I would say that evidence
6 and impact were the -- the main reasons.

7 Q. Okay. Now, I'm pretty sure
8 I know the answer to this question, but
9 I'm going to ask it anyway.

10 In evaluating these measures
11 did you -- did your analysis
12 differentiate in any way between
13 abatement measures that are needed for
14 harms that can be traced back to
15 prescription opioids versus those that
16 are attributable solely to people whose
17 abuse of heroin or other illicit opioids
18 has nothing to do with prescription
19 opioids?

20 MS. RELKIN: Objection to
21 form.

22 You can answer if you can.

23 THE WITNESS: The case that
24 I make in this report is that the

1 increase in the supply of
2 prescription opioids under -- was
3 an underlying factor for the
4 development of additional opioid
5 epidemics, including the heroin
6 epidemic creating a market,
7 increasing the risk among users.
8 And so, I would attribute -- in
9 terms of the overall opioid
10 epidemic, I don't see how one in a
11 public health sense would
12 differentiate between those two.

13 BY MS. WINNER:

14 Q. So you don't think that
15 that's something that would be practical
16 to do, to try to differentiate between
17 those two categories?

18 A. That's not what I said. I
19 don't think one -- I think that these
20 epidemics are so intertwined in terms of
21 their underlying causation, that it's not
22 only -- the practicality of it is not the
23 key aspect. It's the level of evidence
24 for causation.

1 Q. Now, remedial measures that
2 are taken to address the kinds of
3 problems that you've identified in your
4 report are today taken by a variety of
5 different actors, correct?

6 MS. RELKIN: Objection to
7 form.

8 THE WITNESS: I don't know
9 what you mean. Can you define
10 remedial measures?

11 BY MS. WINNER:

12 Q. Well, you identify three,
13 MAT --

14 A. So but -- I'm sorry. Can
15 you define remediation, what you mean by
16 that word.

17 Q. Well, let me change the word
18 if that's giving you a problem.
19 Abatement measures, does that make you
20 feel more comfortable?

21 A. Sure. The three policies
22 and programs that I talk about.

23 Q. Yes. The kinds of programs
24 that you talk about are undertaken in the

1 world by a variety of different actors,
2 correct?

3 A. Can you describe what you
4 mean by actors.

5 MS. RELKIN: Objection to
6 form. Overbroad.

7 BY MS. WINNER:

8 Q. Well, for example there are
9 some things that the federal government
10 implements and pays for, correct?

11 A. Can you give me an example?
12 I can't --

13 Q. You're not aware of any?
14 Are you aware of anything in these
15 categories that the federal government
16 pays for?

17 A. I need -- I need some
18 specifics in terms of what exactly you're
19 referring to in order to answer that
20 question.

21 Q. Are you aware of federal
22 funding for MAT, for example?

23 A. There are reimbursement
24 programs for different levels of

1 treatment that vary across a wide variety
2 of contexts.

3 Q. And that would include MAT,
4 correct?

5 A. So as I've said, I am not
6 sure what you mean by federal funding.
7 There is federal funding for health
8 insurance that is included in what I've
9 outlined here.

10 Q. So federally funded health
11 insurance pays for some of these
12 measures, correct?

13 A. It depends on the -- on the
14 context.

15 Q. Have you ever heard of
16 grants that are made available to local
17 governments to pay for MAT?

18 A. Again, I would need to see
19 some specifics on a particular type of
20 grant. Certainly there are a number of
21 programs that are available to help
22 individuals who are unfortunately
23 addicted to opioids.

24 Q. And there's some things that

1 are -- some abatement measures that are
2 undertaken at the state level, correct?

3 A. I think that there are a
4 broad range of institutions that can
5 participate in reversing the opioid
6 epidemic. What currently occurs in terms
7 of the participation of institutions to
8 reduce the impact of the opioid epidemic
9 and what could possibly occur, -- what
10 I'm addressing here is the evidence for
11 these programs for their ability to
12 reduce the opioid epidemic, and that's
13 what's in the report.

14 Q. Okay. So would it -- based
15 on what you just said, would it be fair
16 to say that what you've done in your
17 analysis, is try to identify needs
18 without necessarily evaluating who would
19 actually satisfy those needs?

20 A. I think what I was asked to
21 do --

22 MS. RELKIN: Objection to
23 form.

24 THE WITNESS: As an

1 epidemiologist, is to evaluate the
2 epidemiological evidence for
3 procedures, policies, and programs
4 that could reduce the opioid
5 epidemic. And that's what I did
6 in the report.

7 BY MS. WINNER:

8 Q. Did you do any analysis that
9 took into account who would be delivering
10 the services that you refer to?

11 A. Again, what -- perhaps it's
12 important that I clarify what
13 epidemiology is. And there's a section
14 in the beginning of the report where I
15 outline what I did in terms of this
16 report and what epidemiological evidence
17 provides for public health evaluation.
18 And so what I did in this report was an
19 aggregate population level analysis of
20 the effectiveness and the potential
21 impact of these programs.

22 Q. Okay. So you did not
23 attempt to figure out -- it wouldn't be
24 part of your job as an epidemiologist to

1 tell us who would be delivering naloxone
2 or -- or who would be providing a MAT
3 to analysis?

4 A. I don't want to make broad
5 statements about things that are never or
6 always part of an epidemiologist's job or
7 my job in particular. What I can speak
8 to is that what I evaluated in this
9 report is that these three programs along
10 with, you know, other programs as well,
11 have the potential to save lives, like
12 actual people's lives.

13 And so how they are
14 delivered, I think, is an additionally
15 important question. But the fact that
16 there are thousands of individuals that
17 we could save right now is more what I'm
18 focused on in terms of public health.

19 Q. Well, I just want to make
20 sure, and we can move on, if -- if I
21 shouldn't be asking you about this. I
22 want to be sure that -- that I'm clear
23 that you were focusing on whether these
24 were good -- these are good things to

1 have, you know, if you don't mind the
2 shorthand -- and I can try to use your
3 words.

4 But they are -- they can be
5 effective programs, as opposed to whether
6 these are things that Cuyahoga County
7 government should be providing to people
8 specifically as opposed --

9 A. So I -- that's not what I
10 said. What I said was what I did in the
11 report was evaluate these programs in
12 terms of the potential, in terms of
13 the -- the epidemiological evidence base
14 for efficacy and impact.

15 Q. Okay. So your focus is on
16 efficacy and impact, not on the details
17 of implementation, correct?

18 A. Again, I -- I would point to
19 the report itself in terms of what I did.
20 I think it's very clearly stated that
21 what I did was -- was provide the
22 evidence from the epidemiological
23 literature about the effectiveness of
24 these programs, and that I also provided

1 for each of the programs my estimation of
2 the number of users that would benefit
3 them in each of the counties. That's
4 what's in the report.

5 Q. Well, let's look, just as an
6 example, Page 38 to 39 of your report
7 where you talk about naloxone
8 distribution. Am I pronouncing that
9 correctly?

10 A. Naloxone, yes.

11 Q. Naloxone.

12 You have a Section F.5.1
13 that talks about naloxone distribution
14 needs in Cuyahoga County and Summit
15 County, correct?

16 A. Yes, that's correct.

17 Q. By the way, I notice that
18 your report switches on Page 35 to 36
19 from numbering that starts with C to
20 suddenly numbering that starts with F.
21 Is there some reason for that?

22 A. That was a typo.

23 Q. Okay. Just wanted to make
24 sure.

1 All right. So in Section F,
2 this is one of the -- section -- the
3 prior -- prior section you talk about --
4 generally about the efficacy of naloxone
5 distribution. And then in Section F.5.1
6 you go on to talk about the need
7 specifically in Cuyahoga County and
8 Summit County, correct?

9 A. So the first part of
10 Section F.5 provides an evidence base for
11 the efficacy of naloxone in reversing
12 potential failed consequences of an
13 overdose. And also, in addition to that,
14 the evidence base that -- that providing
15 expanded access to naloxone also reduces
16 overdose events. So it's really two
17 different statements.

18 Q. But -- but that said, where
19 you talk specifically about the -- trying
20 to quantify needs in Cuyahoga County and
21 Summit County for naloxone, that's
22 Section F.5.1, correct?

23 A. That's correct.

24 Q. Okay. So -- and then you

1 talk about, in that section, you give --
2 you make a number of different
3 observations about -- about the numbers
4 and the needs for naloxone.

5 But I want to focus just on
6 the first instance, in the last
7 paragraph, which is about naloxone
8 administration kits in Cuyahoga County,
9 correct?

10 A. Okay.

11 Q. And in there you say, a
12 couple sentences down -- third sentence I
13 think. This is in -- "This is in
14 addition to medical first responders such
15 as EMS who are trained to administer
16 naloxone, available data indicate that in
17 2018 Cuyahoga County EMS administered
18 naloxone at least 4,353 times."

19 And then you go on with the
20 parenthetical about that. I'm -- I'm
21 focused on this 4,353 number.

22 Does Cuyahoga County
23 actually have EMS services at the county
24 level?

1 A. This statement was based on
2 data that was provided to me.

3 Q. By whom?

4 A. By the counsel.

5 Q. Okay. So -- by counsel, you
6 mean plaintiffs' counsel, not your
7 counsel. We know that.

8 A. That's right.

9 Q. Yes. Okay.
10 So this came from
11 plaintiffs' counsel, correct?

12 A. Yes.

13 Q. Okay. So am I correct that
14 you don't actually know yourself whether
15 Cuyahoga County provides EMS services?

16 A. I evaluated the -- the
17 statement based on what was sent to me.

18 Q. Were you assuming, based
19 on -- on the information that was
20 provided to you by counsel, that Cuyahoga
21 County itself was, in fact, providing EMS
22 services?

23 A. Again, I think what I have
24 in the report is pretty clear. You know,

1 I was sent information -- I asked for
2 information about, you know, providing an
3 estimate of the potential impact in the
4 county and that's the information that
5 was provided to me. And that's what's in
6 the report.

7 Q. So are you purporting
8 here -- I don't want to use the word
9 purporting. That isn't --

10 MS. RELKIN: Objection to
11 form.

12 BY MS. WINNER:

13 Q. I don't -- that -- are you
14 intending here to provide an opinion
15 about the naloxone needs that exist for
16 EMS in the city of Cleveland?

17 A. What I provided was the
18 information that was given to me about
19 the number of administered naloxone
20 distribution based on the information
21 that I was sent.

22 Q. My question though, are you
23 offering any opinions through this report
24 about abatement needs in the city of

1 Cleveland, to be provided for by the city
2 of Cleveland?

3 A. My understanding is the city
4 of Cleveland is in Cuyahoga County; is
5 that correct?

6 Q. That -- last I knew, yes.

7 A. So I would say that that is
8 covered under the estimates that I have
9 provided.

10 Q. If it were demonstrated to
11 you that Cuyahoga County, in fact, does
12 not provide EMS services, would that have
13 any impact on the opinions that you
14 provide in this paragraph?

15 A. I mean, you know, let's --
16 I'm -- I'm -- I keep an open mind to all
17 available evidence. I think the point
18 that I was making in this paragraph is
19 that naloxone is a really important
20 program to reduce overdose. And however
21 it is distributed is how it should be
22 distributed. So if there is new
23 information that I could use, my opinion
24 would not change. Just that distributing

1 naloxone is an important thing to do in
2 Cuyahoga County.

3 Q. Well, you have basically two
4 sets of opinions about naloxone in -- in
5 this report.

6 One set of opinions is about
7 whether naloxone is a good and important
8 thing to have out there. The other set
9 of opinions is about specific numbers,
10 and so I'm trying to focus on your
11 opinions about specific numbers.

12 And so my question is:
13 If -- if -- leaving aside the question of
14 whether, you know it is important for
15 naloxone to be available in the
16 community, would your opinion about the
17 specific needs of Cuyahoga County be
18 affected if you knew that Cuyahoga County
19 does not provide EMS services?

20 MS. RELKIN: Objection to
21 form. Compound.

22 THE WITNESS: Again, I think
23 I would -- I would respond to that
24 by saying what I intended to

1 convey in that paragraph was some
2 assessment of the overall amount
3 of distribution of naloxone that
4 should occur.

5 If there are -- if new
6 information comes to light about
7 specific EMS services, you know,
8 that estimate could be revised.
9 But it doesn't change the overall.

10 That's one sentence in the
11 overall paragraph about the
12 estimated number of naloxone
13 administration kits that I would
14 estimate would be necessary.

15 So, sure, of course, I keep
16 an open mind. If new information
17 is available, I obviously want to
18 present the most accurate picture
19 that I can. But I think the
20 opinion that I have doesn't
21 change.

22 BY MS. WINNER:

23 Q. Do you distinguish in your
24 opinion -- is there a difference in

1 your -- let me start that again.

2 Is there a difference in
3 your view between the amount of naloxone
4 that is needed within Cuyahoga County as
5 opposed to the amount that is needed by
6 Cuyahoga County as a government entity?

7 MS. RELKIN: Objection to
8 form.

9 THE WITNESS: I need more
10 information on your
11 differentiation.

12 BY MS. WINNER:

13 Q. So you can't answer my
14 question without more information?

15 A. I don't understand your
16 question.

17 Q. Okay. Let me ask you about
18 your section about Summit County.

19 You have a similar
20 paragraph, discussing naloxone
21 administration kits in Summit County on
22 the next page, correct?

23 A. Mm-hmm.

24 Q. And do you know -- and that

1 includes, among other things -- there are
2 other things in here. But one of the
3 things that's in there is you have an
4 estimate of the amount of naloxone that
5 is needed for EMS in Summit County,
6 correct?

7 A. So what I have in here is,
8 "Data are not currently available to me
9 regarding the total number of first
10 responders in Summit County; however, the
11 Akron Fire Department has a current work
12 force of approximately 354 individuals,
13 and there are 14 EMS/paramedics," and I
14 have a citation that was provided to me.

15 "Available data indicate
16 that in 2018 Summit County EMS
17 administered naloxone at least 1,562
18 times. This is likely an underestimate
19 because 81.8 percent of EMS agencies
20 reported."

21 Q. Is there such a thing as
22 Summit County EMS?

23 A. Again, I don't -- this is
24 the information that was provided to me.

1 If new information comes to light, it
2 doesn't change my opinion that naloxone
3 is very much needed in communities that
4 have a high burden of opioid overdose.

5 Q. You say this was information
6 that was provided to you. Again, was it
7 provided to you by plaintiffs' counsel?

8 A. That's correct.

9 Q. You -- in what you just
10 read, there's a reference to the Akron
11 Fire Department.

12 A. Yes. The Akron Fire
13 Department has a current --

14 Q. I don't need you to read it
15 again. Is the Akron Fire Department an
16 agency of the Summit County government?

17 A. This is the information that
18 was provided to me. I can -- we can go
19 to Reference 195 and look at the
20 information.

21 I asked plaintiffs' counsel
22 for information on these different
23 workforce numbers. And these are the
24 numbers that I relied on. Should new

1 information come to light, again, the
2 opinion is the opinion. I think
3 providing an estimate for these specific
4 counties is -- is what I was endeavoring
5 to do in these paragraphs.

6 Q. Do you know whether the
7 Akron Fire Department carries naloxone
8 today?

9 A. That information was not
10 provided to me.

11 Q. If -- well, I assume the
12 answer is going to be the same. But let
13 me just ask it.

14 Assuming that the Akron Fire
15 Department does carry naloxone, do you
16 know who pays for it?

17 A. In the -- I'm sorry, this
18 pen is really leaking.

19 In the information that was
20 provided to me, the source of funding for
21 each individual naloxone kit was not
22 included.

23 Q. Now, in Section C.3 of your
24 report -- let's go back. It starts on

1 Page 32. You provide estimates of the
2 numbers of persons in each of these two
3 counties who were currently living with
4 opioid use disorder, correct? I'll
5 direct you to the last paragraph on Page
6 32, the first sentence.

7 A. Yes. "While the number of
8 individuals currently living with opioid
9 use disorder in Cuyahoga and Summit
10 Counties is unknown, I can provide an
11 estimate of the number, given number the
12 overdose deaths."

13 Q. And you -- is the estimate
14 that you then -- and we'll walk through
15 this. But is the estimate that you then
16 go on to provide intended to be
17 specifically an estimate of the number of
18 individuals in each county who is
19 currently living with opioid use
20 disorder?

21 A. Depend -- so the paper that
22 I relied onto make that assessment looked
23 at individuals who were dependent or
24 regular users of opioids.

1 Q. Is that the same thing as
2 people who have opioid use disorder?

3 A. So this is the information
4 that I thought was important to gather an
5 estimate of the number of individuals who
6 would be in need of these services.

7 Q. But my question is --

8 A. It would be inclusive of
9 opioid use disorder.

10 Q. But is opioid use disorder
11 the same thing as being a dependent or
12 regular user of opioid?

13 A. So the Degenhardt, et al.,
14 2011 paper did not is assess opioid use
15 disorder. The Degenhardt paper assessed
16 dependent or regular users of opioids.
17 And I used that paper to provide an
18 estimate of the number of individuals in
19 those counties who would be in need of
20 these services, and would include
21 individuals living with opioid use
22 disorder.

23 Q. Is it limited to people who
24 have opioid use disorder or is it

1 broader?

2 A. The estimate is individuals
3 who are dependent or regular users of
4 opioids.

5 Q. Is that likely to be
6 broader, narrower, or the same as the
7 population of people with opioid use
8 disorder?

9 A. Let's see. Individuals who
10 are dependent, so -- and regular users of
11 opioids. I would estimate that it's
12 largely similar.

13 Q. How similar? Do you have a
14 confidence interval or anything like that
15 for that?

16 A. I would need to do a
17 statistical analysis for that.

18 Q. Okay. I'd like to show you
19 what's been previously marked as
20 Exhibit 13 to your deposition, which I'm
21 hoping is the article that you're talking
22 about.

23 (Document marked for
24 identification as Exhibit

1 Keyes-13.)

2 BY MS. WINNER:

3 Q. And is Exhibit 13 in fact
4 the article that you referred to a second
5 ago as the one that you relied upon for
6 this calculation?

7 A. So this article, just to be
8 clear, is a random effect meta-analysis
9 for the mortality, the crude and
10 standardized mortality rates for
11 individuals who are dependent or regular
12 users of opioids.

13 Q. Okay.

14 A. And I relied on it for this
15 assessment.

16 Q. Okay. And this is -- this
17 is the article that you cite in this
18 section of your report? I think it's --

19 A. I cite this article in this
20 section of the report.

21 Q. And it is, I think, just for
22 the record, this is Reference 151.

23 A. Let me just double-check
24 that.

1 Q. Sure.

2 A. Yes, it is Reference 151.

3 Q. What you pulled out of this
4 report, am I correct -- well, first of
5 all, let's just talk about what this is.

6 This is a -- and I don't
7 want to go into every detail of it. But
8 generally this is a review of multiple
9 studies that evaluates their results on
10 the subject of mortality, correct?

11 A. So the outcomes reported
12 here are two outcomes. One is the crude
13 mortality rate. And one is the
14 standardized mortality rate for specific
15 causes of death across studies that used
16 inclusion criteria -- I'm sorry, that
17 used exclusion criteria that included not
18 reporting heroin or opioid users,
19 opioid-related mortality, or not reported
20 research data or case studies.

21 So that is what the design
22 was, was a multiple search strategy to
23 find studies that assessed mortality
24 among regular and dependent users of

1 opioids.

2 Q. And that is what is
3 identified under aims in the first
4 sentence of the abstract on the first
5 page, correct?

6 A. So the aims that are listed
7 in the abstract are broader than just
8 mortality among dependent or regular
9 users of opioids across regions. They
10 also list according to specific causes
11 and related to demographic and clinical
12 variables.

13 Q. Now, the aims for this
14 review did not include developing a
15 methodology for calculating the size of
16 drug user population, based on overdose
17 numbers, is it?

18 A. This specific article is an
19 article that provides a meta-analytic
20 estimate of the association between
21 dependent and regular use of opioids and
22 mortality as well as specific causes of
23 death.

24 Q. Is that your complete answer

1 to my question?

2 A. Is that -- does that not
3 answer your question?

4 Q. Well, my question was, the
5 aims for the review did not include
6 developing a methodology for calculating
7 the size of drug user population based on
8 overdose numbers.

9 A. I can show you what the aims
10 of the study are. I used the study in my
11 estimation in the -- the report that I
12 developed.

13 Q. We'll talk in a minute about
14 what you did. I'm -- my first question
15 is what was the -- well, whether that was
16 the purpose of this particular study.

17 A. The purpose of this
18 particular study was to provide a
19 meta-analytic estimate of the association
20 between regular and dependent use of
21 opioids and mortality as well as all
22 specific mortality.

23 Q. If you turn to Page 45 of
24 Exhibit 13. The second column, first

1 full paragraph.

2 The second sentence here
3 says, "Pooled estimates suggested that
4 overdose-related mortality was the most
5 common specific cause at 0.65 deaths per
6 100 PY." And there's a confidence
7 interval after that.

8 And then the sentence go
9 on -- goes on to talk about TMRs for
10 other -- for other things.

11 Is the -- the first portion
12 of that sentence that I just read, is --
13 was -- is that your source for the .65
14 deaths per 100 PY that you use in your
15 report?

16 A. There's also a confidence
17 interval from .55 to .75.

18 Q. Yes.

19 A. Just to note that.

20 Q. But -- but am I -- have I
21 identified the -- the place in this, in
22 Exhibit 13 where you got those numbers?

23 A. That's correct.

24 Q. So is this saying that there

1 were -- well, first of all, when it talks
2 to -- when it says pooled estimates, is
3 that talking about aggregating the
4 results from all of the studies that are
5 addressed in this analysis?

6 A. So the methodology for
7 pooling, I believe, is described in the
8 methods section.

9 So it's a little broader
10 than just aggregating.

11 Q. Well, let me -- let me ask
12 it a different way. Maybe -- maybe this
13 will make it a little easier.

14 This .65 is not derived from
15 any single study that's addressed in this
16 analysis, it's -- it's drawn from a
17 broader pool of studies, correct?

18 A. So that's what meta-analysis
19 does. And I -- it's outlined in the
20 definition of my report.

21 We rely on meta-analyses
22 as -- you know, when there are a number
23 of studies that have been conducted on a
24 similar issue, you know, we might think

1 that any one particular study, you might
2 be over or slightly under due to random
3 error or, you know, any number of
4 different reasons. And so in a
5 meta-analysis, what you do is take all
6 the studies on a particular topic and
7 then provide a summary estimate of them.
8 That is the intention of the analysis.

9 Q. And -- and you would
10 consider this an epidemiological -- I can
11 never pronounce that word. You are
12 obviously used to it.

13 For your field, this is an
14 epidemiological study, or analysis, or
15 review, or whatever the word would be?
16 This is in your -- this comes from your
17 field, this particular paper here?

18 A. I guess my question is, what
19 do you mean by my field?

20 Q. Well, you are an
21 epidemiologist, correct?

22 A. I am an epidemiologist, yes.

23 Q. And -- and is this a paper
24 from epidemiology?

1 A. I would say that this paper
2 uses epidemiological studies in order
3 to -- you know, meta-analysis is used --
4 a lot -- I wouldn't claim it for
5 epidemiology. But this particular paper
6 uses epidemiological data.

7 Q. So this -- am I correct
8 that, that what this paper is finding is
9 that there were .65 deaths per 100 person
10 years during which the subjects of the
11 studies were observed?

12 A. I'm sorry, I'm just going to
13 go to the place where that is written.

14 Can you point again to the
15 page number?

16 Q. Sure. Page -- it's -- we're
17 on Page 45.

18 A. Sorry.

19 Okay. So what this study
20 said in the results section is that
21 "pooled estimates suggested that overdose
22 related mortality was the most common
23 specific cause at .65 deaths per 100,000
24 person years."

1 So your question is?

2 Q. I'm just trying to translate
3 that into more everyday English. Does
4 that mean that --

5 A. If 100 people were observed
6 for one year, you would expect there to
7 be .65 overdose deaths.

8 Q. Thank you. That's helpful.

9 And that is the -- that .65
10 figure is the number that you then went
11 on to use to apply to overdose statistics
12 to estimate the populations in each of
13 those -- these who had counties overdose
14 related --

15 A. I used that as a -- and its
16 related confidence interval, to provide
17 an estimate of the number of dependent or
18 regular users of heroin -- I mean of
19 opioids.

20 Q. Now, the -- who are the --
21 the subjects of these studies? Is -- and
22 I'm not asking you to list them all. Am
23 I correct that they are described in the
24 tables that -- the table that starts, I

1 guess it's on Page 35, Table 1?

2 A. Okay. So Table 1 is
3 included... studies investigating all
4 cause mortality.

5 And so table 2 then is
6 cohorts purporting proportion of deaths
7 due to AIDS, overdose, suicide, and
8 traumatic causes of death.

9 Q. I'm -- I'm more focused on
10 the nature of the -- I think it's the
11 nature of the sample column.

12 No, who -- who were the
13 people who were in these studies?

14 MS. RELKIN: Objection.

15 Form. Overbroad.

16 There's multiple studies.

17 Do you want her to go through each
18 one?

19 BY MS. WINNER:

20 Q. Do you see on Table 1
21 there's a column that says nature of
22 sample?

23 A. So -- yeah, you know, again,
24 I -- you really should look at Table 2,

1 because that's where --

2 Q. Okay.

3 A. -- the overdose deaths are
4 provided.

5 Q. Well, no, I -- my question
6 is different. I -- I am trying to
7 focus -- and again, without focusing on
8 any particular study, is there any place
9 in here where we can see who the people
10 were in the studies. Were they heroin
11 users, were they injecting heroin users,
12 were they -- were they users of all
13 drugs?

14 A. So do you want me to go
15 through each one?

16 Q. No, I don't want you to go
17 through each one. I want to know, is
18 there someplace that we can look that up?
19 Is there -- is that in Table 1?

20 A. So it -- Table 1 lists the
21 publication near the region, the country,
22 the year, the nature of the sample.

23 However, I just want to
24 point out that the -- the studies that

1 were actually used for the overdose
2 estimate are in Table 2.

3 Q. Understood. But Table 2
4 doesn't separately list -- describe the
5 population of the -- of the subjects in
6 each of the studies, does it?

7 A. No, it does not.

8 Q. Now, am I correct that
9 this -- Exhibit 13 is the only source
10 that you cite for this .65 per 100 and
11 confidence interval in your -- in your
12 report?

13 A. Well, that's a bit of a
14 simplification because the -- the paper
15 itself is a meta-analysis. So I was
16 relying on the -- the evidence that was
17 used to meta-analyze that source.

18 Q. But you were relying on the
19 meta-analysis, not on any of the
20 individual analyses that -- that are in
21 the underlying studies, correct?

22 A. That's correct.

23 Q. Now, your report in this
24 case does not cite any literature in

1 which this .65 statistic has been used
2 for the purpose of estimating the size of
3 an opioid dependent population, have you?

4 A. So --

5 MS. RELKIN: Objection to
6 form.

7 THE WITNESS: -- what I
8 provided in the report was not
9 only my estimate based on -- on
10 using this meta-analysis, but also
11 what -- comparing it to the
12 National Household Survey on Drug
13 Use and Health, which is on
14 Page 33.

15 BY MS. WINNER:

16 Q. Now that's a different --
17 I'm asking you a different question.

18 A. Okay.

19 Q. My question is, do you cite
20 any literature where anybody else has
21 used this .65 number out of Exhibit 13
22 for the purpose you use it for in this
23 report?

24 A. I think my report is very

1 clear about what my methodology was in
2 using that estimate. The use of
3 estimates is a very standard practice in
4 the epidemiological literature. And to
5 extract a population size based on
6 published estimates is a methodology
7 that's commonly used in epidemiology.

8 So the methodology itself is
9 something that is something that I have
10 expertise in and that is commonly used in
11 the peer-reviewed literature.

12 Q. My question was a little
13 different. My question was, is there
14 anybody else who has ever used this,
15 Exhibit 13, this particular number that
16 you took out of Exhibit 13, for the
17 purpose of estimating the size of an
18 opioid dependent population?

19 MS. RELKIN: Objection to
20 form.

21 THE WITNESS: I think I've
22 answered the question. I've
23 outlined in my report how I use
24 the estimate. I have outlined in

1 the report the way the methodology
2 is used. The methodology that I
3 used is standard practice in the
4 epidemiological literature.

5 As far as any one particular
6 study that has used this estimate
7 in and of itself, I don't have a
8 specific citation in the report.
9 But it is a standard way to
10 evaluate population sizes in the
11 epidemiological literature.

12 BY MS. WINNER:

13 Q. Okay. But I want to follow
14 up on what you just said. You don't have
15 a specific -- I don't have a specific
16 citation in the report, but it is a
17 standard way to evaluate population sizes
18 in the epidemiological literature.

19 I just want to focus -- when
20 you say it is a standard way, are you
21 talking about --

22 A. I'm talking about the method
23 and not this particular number.

24 Q. Got it.

1 MS. DO AMARAL: Counsel, is
2 it a good time for us to take a
3 break?

4 MS. WINNER: Sure, no
5 problem.

6 THE VIDEOGRAPHER: The time
7 is 4:18 p.m. Going off the
8 record.

9 (Short break.)

10 THE VIDEOGRAPHER: The time
11 is 4:32 p.m. Back on the record.

12 BY MS. WINNER:

13 Q. Okay. Before the break, we
14 were discussing the calculations you did
15 in Section C.3 of your report.

16 A. Yes.

17 Q. Correct?

18 And am I correct that you
19 took this .65 per 100 person-year number,
20 and you then applied that to the overdose
21 deaths in 2013 in each of the two
22 counties to estimate the opioid dependent
23 or regular user population in each
24 county?

1 A. That's correct.

2 Q. And the overdose death
3 statistics from those counties that you
4 used included all drug overdoses, not
5 just opioid overdoses, correct?

6 A. So just to be clear, that
7 is -- the reason for that is because the
8 Degenhardt meta-analysis looked at all
9 drug overdose deaths among regular or
10 dependent users. And so to provide a
11 comparable analysis, I needed to use all
12 drug overdose deaths in the counties.

13 Q. But those were all drug
14 overdose -- okay. Strike that.

15 Let me try to streamline
16 this a little bit. Let's go back to
17 Degenhardt. Is that an appropriate way
18 to refer to Exhibit 13. If you would
19 turn back to the abstract. Near the
20 bottom there is a sentence that reads, "A
21 multi-variable regressions found the
22 following predictors of mortality rates:
23 Country of origin, the proportion of
24 sample injecting, the extent to which

1 populations were recruited from an entire
2 country versus sub-national, and year of
3 publication."

4 Did I read that correctly?

5 A. You read that statement
6 correctly. I'd like to go just to the
7 methods section to make sure that --
8 because sometimes in abstracts it's an
9 oversimplification of what was done.

10 Q. Okay. Is there something
11 inconsistent? I assume you studied this
12 study fairly carefully before you used
13 it.

14 A. I did study -- I did study
15 it carefully, but with over 200
16 citations, I just want to be sure that we
17 don't abstract something from an abstract
18 that is defined more carefully in the
19 paper itself.

20 Okay. So on page 43, I
21 think they provide more information on
22 study covariates. So the proportion of
23 the sample injecting was included in the
24 covariate as a continuous variable at a

1 bivariable level. Study is conducted in
2 countries low and middle income. Low
3 case ascertainment. High percentage of
4 sample injecting.

5 So yes.

6 Q. All right. Then there's a
7 section called "Limitations" on Page --
8 starting on Page 46. I've seen a section
9 entitled "Limitations" in a number of the
10 studies that you've cited. Is that a
11 common section to include in an article
12 like this?

13 A. Yes.

14 Q. And what is the author
15 generally -- what is the purpose of a
16 Limitations section in a paper like this?

17 A. Generally, in
18 epidemiological studies, the purpose of a
19 limitations section is to provide the
20 reader with any additional information
21 that would aid in their interpretation of
22 the paper and to provide an opportunity
23 for the author to provide additional
24 information on the robustness of their

1 results to any particular limitation of
2 the methods, data source, et cetera.

3 Q. Well, the first paragraph
4 under limitations here says that, "The
5 studies reviewed here differed
6 considerably. The length of follow-up of
7 the cohorts ranged from one to 36 years.
8 This is problematic, because drug use can
9 change over time period, and this can
10 affect mortality rates."

11 I'll stop there.

12 Do you think that that is an
13 accurate statement of a limitation of
14 this review?

15 A. I would say that -- I would
16 say that that is an accurate limitation
17 of the review. But again, applying it in
18 the way that I did in the report, I think
19 you provide a confidence interval around
20 the estimate. You know, that's the best
21 available estimate for the rate of the
22 standardized mortality ratio for a
23 dependent user.

24 So I think that even though

1 there is heterogeneity, to use that word
2 again, there are differences in the
3 length of follow-up of the cohorts from
4 one to 36 years.

5 When you meta-analyze
6 something, you're aggregating across all
7 of that.

8 Q. Sometimes when you aggregate
9 over a heterogenous set of data, you can
10 gloss over variations, meaningful
11 variations within the data, correct?

12 MS. RELKIN: Objection to
13 form.

14 THE WITNESS: So anytime we
15 provide, you know, this is what
16 epidemiology does. We provide
17 aggregate estimates of risk. We
18 don't provide estimates at the
19 individual level. So we're always
20 aggregating to provide an
21 assessment of risk factors.

22 You know, the overdose
23 deaths in the counties are also an
24 aggregate of a lot of individuals.

1 BY MS. WINNER:

2 Q. But aggregation can be --
3 the reason heterogeneity is identified as
4 a limitation here, is because, or at
5 least in part because aggregate -- it
6 means that aggregation can yield results
7 that are less meaningful?

8 A. I don't necessarily think
9 that that is -- it really depends on what
10 the research question you're asking is
11 and what you're using those data for, in
12 terms of the meaningfulness of
13 aggregation. Sometimes we want an
14 aggregate estimate of the average risk of
15 a certain outcome across the heterogenous
16 subgroups that make up that average risk.

17 Q. Have mortality rates from
18 overdose deaths in the drug using
19 population changed over time?

20 A. Over what time period
21 specifically?

22 Q. Over any time period over
23 the last 20 years?

24 A. So specifically in the last,

1 you know, three years since 2013,
2 mortality rates have increased.

3 Q. And did mortality rates
4 change in the time period before the last
5 three years?

6 A. The mortality rates, the
7 overall population mortality rate due to
8 overdose has changed. Is your question
9 about changes over -- can you be specific
10 about the population with which you're
11 asking the question.

12 Q. Okay. That's a fair
13 question. Let's start with the overall
14 population mortality rate has changed
15 over time, has it not?

16 A. The overall population
17 mortality rate of --

18 Q. For overdose?

19 A. For overdose has increased.

20 Q. Has the overall mortality
21 rate varied over time before the past
22 three years among opioid users?

23 A. You know, I would have to go
24 to meta-analysis in order to answer that

1 question.

2 You're asking about the
3 United States?

4 Q. Yes.

5 A. So let's see if there are
6 U.S. studies --

7 Q. Well, let me just ask, is
8 that something you've looked at before I
9 asked you that question just now?

10 A. What the variation over
11 time -- so what I used as a meta-analysis
12 that pooled data across a number of
13 different studies. To the extent that
14 there are U.S. studies involved in that
15 particular estimate, I don't believe that
16 there are, but I would like to just
17 confirm.

18 So the meta-analysis used
19 three different studies from North
20 America, from the United -- no, I'm
21 sorry, four different studies -- I
22 apologize again. No, that's from Canada.

23 So there are a number of
24 studies cited in here. One is based in

1 California. One is based in Albuquerque.
2 One is among Vietnam veterans. And
3 overall it does not provide data on
4 whether the overdose rate among those
5 different populations have changed over
6 time.

7 So as far as I know, you
8 know, the -- the overdose rate among
9 regular or dependent users of opioids in
10 the United States has not been
11 systematically investigated.

12 Q. Now, you do however have an
13 opinion that the mortality rate has
14 changed in the past three years because
15 of the fentanyl problem?

16 A. The population mortality
17 rate has.

18 Q. The population mortality.
19 Is that also true of the --
20 the opioid using population mortality
21 rate?

22 MS. RELKIN: Objection to
23 form.

24 THE WITNESS: So I'm sorry,

1 your question is whether there is
2 available data on the overdose
3 rate from fentanyl among opioid
4 users?

5 BY MS. WINNER:

6 Q. Let me -- let me -- let me
7 take a step back and ask a different
8 question.

9 If the -- some opioids, if
10 abused, are more lethal than others,
11 correct?

12 A. It depends on the amount,
13 the dose, and the duration of use.

14 Q. But -- but in terms of --

15 A. I wouldn't make -- I just --
16 I wouldn't make a blanket statement about
17 products and their overdose potential.

18 Q. Well, do you believe, based
19 on the data you've seen that illicitly
20 manufactured and sold fentanyl that's
21 used to adulterate heroin and cocaine and
22 other drugs, is -- contributes to more
23 overdose deaths than abuse of Vicodin for
24 example?

1 MS. RELKIN: Objection to
2 form. You can answer.

3 THE WITNESS: What I can
4 say, with respect to the
5 epidemiological data that is
6 available that I have reviewed, is
7 that there has been an increase in
8 fentanyl associated overdose
9 deaths.

10 Your second question is
11 whether there are more deaths than
12 Vicodin deaths?

13 BY MS. WINNER:

14 Q. Is it more dangerous for a
15 person, to you, based on the
16 epidemiological evidence, if there is
17 any, is it more risky to use heroin that
18 may be laced with fentanyl, than it is to
19 use Vicodin?

20 A. It would depend on the dose
21 of -- of each substance that was used.

22 Q. So you are not aware of any
23 general epidemiological evaluation that
24 is made about the -- the aggregate

1 riskiness of one opioid versus another?

2 A. No. That's not what I'm
3 saying. What I'm saying is that the
4 aggregate riskiness of all opioids is
5 dependent on the dose and duration, and
6 the potency of the opioid differs across
7 product.

8 So I wouldn't make a
9 comparison between one or the other
10 without knowing what potency, dose and
11 duration are used.

12 Q. And is that something that
13 then has to be evaluated at the
14 individual level rather than at a
15 population level?

16 MS. RELKIN: Objection to
17 form.

18 THE WITNESS: The -- so the
19 question is at a population level,
20 could you -- could one evaluate
21 the overdose risk of various
22 opioid products at -- at various
23 levels of dose, duration, and
24 potency?

1 BY MS. WINNER:

2 Q. Yes.

3 A. Yes, you --

4 Q. Has that been done?

5 A. I know of a number of
6 studies that have looked at the
7 relationship between dose of a number
8 different products in overdose risk that
9 I've cited in the report. I don't know
10 of any that specifically compared to
11 other opioid -- to fentanyl-related
12 products.

13 Q. Do you know of any studies
14 that -- that took into account for
15 example, risks associated with taking a
16 street drug that -- that you can't be
17 sure of the dosage or the purity of, as
18 opposed to a pill that you know what
19 the -- how much you're taking?

20 MS. RELKIN: Objection to
21 form.

22 THE WITNESS: So the
23 question is, is there -- can you
24 ask the question -- I don't quite

1 understand what you're asking.

2 Are street drugs more dangerous
3 than --

4 BY MS. WINNER:

5 Q. Are street -- are street
6 drugs like heroin more dangerous than,
7 you know, a bottle of -- of pills from a
8 pharmacy?

9 A. I don't --

10 Q. If abused.

11 A. I think comparing those two
12 would be apples and oranges, because
13 physicians were misinformed about the
14 risks of harms associated with
15 prescribing prescription opioids.

16 So yes, when you're using
17 drugs that are bought and sold on the
18 street, there might be more -- there may
19 be more variation with respect to purity.

20 Q. Well, and one of the
21 variations in purity is that some of it
22 is adulterated with illicit fentanyl,
23 correct, for heroin?

24 A. Well, for prescription

1 opioids as well.

2 Q. What -- do you have any
3 statistics on the percentage of
4 prescription opioids that people buy
5 thinking they are buying a prescription
6 opioid that is -- that's adulterated with
7 fentanyl?

8 A. So there is a study that has
9 examined this. And I cite it in the
10 report that I can pull out for you.

11 Q. Can you just tell me the
12 section? We don't need to -- if you can
13 just cite it to me, I can go look it up
14 later.

15 A. Yeah, let's see. I believe
16 it is in the overdose section. I believe
17 the CDC has put out a publication on that
18 topic.

19 If I can point you to the
20 exact. I believe that Reference 62 has
21 that information.

22 Q. Okay. Thank you.

23 A. I can confirm.

24 Q. I -- like my colleague, I

1 have limited time. So let's go onto
2 something else.

3 You were asked a number of
4 questions earlier about Figures 3, 4 and
5 5 in your report. Do you recall that?

6 I'm sure you recall that,
7 that wasn't that long ago.

8 A. I do recall that.

9 Q. I just have a -- a quick
10 follow-up question on that.

11 Let's just focus on -- well,
12 any of them. But they all end in 2017,
13 correct?

14 A. Yes.

15 Q. Did you review statistics of
16 overdose death rates in these two
17 counties in 2018?

18 A. At the time that we put
19 these figures together the publicly
20 released data was included up until 2017,
21 and we used the publicly available county
22 level data for this report.

23 Q. Have you reviewed that data
24 since then?

1 A. I have not gone back to the
2 data since then.

3 Q. Have you seen information
4 indicating that overdoses in Cuyahoga
5 County were down by more than 20 percent
6 from 2017 to 2018?

7 A. As I -- as I said I have not
8 reviewed the 2018 data to my knowledge.
9 I did review -- the CDC put out a
10 publication, I think preliminary data on
11 2018, but did not put it out at the
12 county level. So we can look at -- I
13 mean, what -- what is available is the
14 overall national statistics. But the
15 county level data, I would need to see --
16 to evaluate the validity of that
17 statement, I would need to see the data.

18 Q. I'm not asking you to take
19 my word for it.

20 Let's look at Page 34 of
21 your report. Wait a minute. I'm in the
22 wrong section.

23 Where is this?

24 Here it is. I found it.

1 Okay. Page 34. I am on the right page.
2 In the section near the top on Summit
3 County, do you see that? There's a
4 paragraph on Summit County?

5 A. Yes.

6 Q. The last sentence of that
7 section says, "Available data in Summit
8 County indicates that MAT utilization is
9 not currently adequate for abatement and
10 treatment of those in need. Available
11 data indicate that there were 2,072
12 individuals receiving MAT in Summit
13 County."

14 Do you see that?

15 A. Yes.

16 Q. Did I read it correctly?

17 A. Yes.

18 Q. Now, what is -- the number
19 2,072 is lower than the number that you
20 come up with as the -- the population
21 size for Summit County, the relevant
22 population size for Summit County,
23 correct?

24 A. So using the anticipated

1 death rate of .65 per 100,000
2 person-years, I estimate the total size
3 at 11,538.

4 Q. Is there anything other than
5 the difference in those two numbers that
6 you rely on in stating that available
7 data in Summit County indicates that MAT
8 utilization is not currently adequate for
9 abatement?

10 A. That is the data that I
11 relied on. The comparison of those two
12 numbers, in order to -- again, the
13 overall picture to paint in that
14 paragraph is that there's a large number
15 of people who are suffering who are in
16 need of additional attention.

17 Q. Now, you refer in that
18 sentence to MAT utilization, correct?
19 You say MAT utilization is not currently
20 adequate, correct?

21 A. MAT utilization is the
22 phrase that I use.

23 Q. Yes. To say that MAT
24 utilization is not adequate is not

1 necessarily the same thing as saying MAT
2 resources are not adequate, correct?

3 A. The data that were provided
4 to me were the number of individuals
5 receiving MAT in Summit County. And so
6 that is what I used to make that
7 statement.

8 Q. Do you know how many people
9 the MAT resources in Summit County that
10 exist today would be able to accommodate?

11 A. Those -- I have not seen
12 those data.

13 Q. Now, your reference for, at
14 the end of that sentence, is -- I assume
15 it's your reference for the 2,072 number,
16 is Reference 158. Can you tell me what
17 Reference 158 is?

18 A. Smith, D., County of Summit
19 Alcohol, Drug and Addiction and Mental
20 Health Services Board.

21 Q. What is that?

22 A. I would need to pull the
23 reference in order to --

24 Q. By all means.

1 A. 158.

2 So reference 158 includes --

3 Q. I'd like to mark that as an
4 exhibit. This was something that was
5 completely unidentifiable from the
6 referenced cites. So I have no idea what
7 it is. So can we mark this as an
8 exhibit.

9 MS. RELKIN: Do you want us
10 to make a copy? Do you want to
11 move to another question, and
12 we'll come back to it.

13 MS. WINNER: Sure. Let's
14 put the sticker on it.

15 (Document marked for
16 identification as Exhibit
17 Keyes-14.)

18 BY MS. WINNER:

19 Q. And Exhibit 14, just so
20 we're clear in case we run out of time
21 before we get back to it. Exhibit 14 is
22 the Reference 158?

23 A. That is Reference 158.

24 Q. And that's where you got

1 that 2,072 number from?

2 A. I believe so. I would --
3 I'll review it again when it comes back.

4 Q. Okay. Do you know -- well,
5 is it a part -- was it any part of your
6 analysis to evaluate whether the grant
7 funding and insurance funding that is
8 currently available in Cuyahoga County
9 and Summit Counties are sufficient to
10 cover the cost of the amount of MAT
11 that's needed?

12 A. So what I have in the report
13 is the assessment of the total population
14 who would be in need of services. I do
15 not have information on grant funding. I
16 would point out that if there are more
17 spots available than people who need
18 them, then additional resources should be
19 placed into getting those people into
20 treatment.

21 Q. Now, it is not in fact
22 possible to get everybody into treatment,
23 correct?

24 MS. RELKIN: Objection to

1 form.

2 THE WITNESS: I don't want
3 to speculate about the
4 possibilities of getting
5 individuals into treatment.

6 BY MS. WINNER:

7 Q. Well, are you aware that
8 some people who are offered treatment
9 refuse it?

10 A. I do know that some people
11 who are offered treatment refuse it.

12 Q. And the law does not
13 allow -- typically allow people to be
14 forced into treatment against their will,
15 does it?

16 A. That's correct.

17 MS. RELKIN: Objection.

18 BY MS. WINNER:

19 Q. So even if there is a need
20 for more people to get MAT than are
21 currently getting it, that doesn't
22 necessarily mean that more MAT resources
23 are needed?

24 MS. RELKIN: Objection to

1 form, misstates --

2 THE WITNESS: So that's not
3 what I'm evaluating in the report.
4 So what I'm evaluating in the
5 report is the total number of
6 people based on the criteria that
7 I've written out that I think
8 could benefit. There is a body of
9 literature that one could bring to
10 bear on motivation to change.
11 Some of the harm reduction
12 techniques that I've outlined in
13 here are actually facilitators for
14 doing that. And so I think
15 that -- I don't want to speculate
16 about who is and who isn't forced
17 to treatment, when there's
18 resources that could be provided
19 to save the lives of the
20 individuals in these counties.

21 BY MS. WINNER:

22 Q. Now, are you offering an
23 opinion based on your analysis that all
24 individuals who have opioid use disorders

1 should be prescribed medication-assisted
2 treatment?

3 A. That is not what is written
4 in my analysis.

5 Q. And is that your opinion?

6 A. Is it my opinion that all --

7 Q. All --

8 A. -- people -- say that again.

9 Q. With opioid use disorder
10 should be given medication-assisted
11 treatment?

12 A. I think what I've outlined
13 in this report is that there's a wide
14 range of treatment options. I don't want
15 to make any recommendation for any
16 individual patient. I'm looking at
17 population level data.

18 Q. Have you done any estimate
19 of what percentage of the overall
20 population in these counties, medication
21 assisted treatment, would be suitable
22 for?

23 MS. RELKIN: Objection to
24 form.

1 THE WITNESS: So again, what
2 I'm providing in this report is an
3 overall assessment of the
4 population of individuals who
5 would benefit from recovery from
6 regular dependent use of opioids.

7 Any one particular patient
8 and their suitability is not what
9 I'm looking at in the report. It
10 is the overall population level.

11 BY MS. WINNER:

12 Q. Okay. But you've given us
13 the pop -- the total pop -- your estimate
14 of the total population of people with
15 opioid use disorder. I think it's
16 actually, an estimate of people who
17 have -- who are dependent or regular
18 users of opioids, correct?

19 A. That's correct.

20 Q. And then you've said that
21 MAT is suitable for at least some people,
22 correct?

23 MS. RELKIN: Objection.

24 THE WITNESS: So what I say

1 in the report with respect to
2 suitability is -- I say, I would
3 estimate that the total size of
4 dependent or regular users of
5 opioids is between 45,343 and
6 52,307 and that this is the number
7 of individuals who are in need of
8 MAT access, not suitability.

9 BY MS. WINNER:

10 Q. Okay. So you're saying
11 these are people who should have access
12 to MAT if it's suitable for them?

13 MS. RELKIN: Objection to
14 form.

15 THE WITNESS: I would say
16 that each patient -- what I said
17 is they should have access to MAT
18 services and that whether someone
19 is suitable or not suitable for
20 MAT is a different research
21 question that I'm not evaluating
22 in that section.

23 BY MS. WINNER:

24 Q. Are you suggesting that

1 investments should be made in a larger
2 capacity for MAT services than are
3 actually needed in the community?

4 MS. RELKIN: Objection to
5 form.

6 THE WITNESS: What I'm
7 saying is that I'm providing an
8 estimate of the total size of
9 regular or dependent users that
10 may be in need of MAT access.

11 BY MS. WINNER:

12 Q. But not everybody in that
13 population is, in fact, going to be
14 suitable for that --

15 A. I don't have that
16 information. I am not evaluating that
17 question.

18 Q. Now, just to close this off.
19 Am I correct that you have not evaluated
20 who actually delivers MAT services in
21 Summit County or Cuyahoga County?

22 A. What I provided --

23 MS. RELKIN: Objection.

24 Asked and answered.

1 THE WITNESS: What I
2 provided in the report is an
3 assessment of the overall MAT
4 access. The overall size of the
5 dependent or regular user of
6 opioids in the counties based on
7 the methodology I described.

8 BY MS. WINNER:

9 Q. But my question is have you
10 evaluated who actually delivers MAT in
11 these counties.

12 A. That information is not
13 available -- was not available to me.

14 Q. Now, you go on then to talk
15 about certain specific populations,
16 pregnant women, people involved in the
17 child welfare system, and -- and jail
18 inmates, correct?

19 A. Yes.

20 Q. Are all of those
21 subpopulations included in the numbers
22 for the county of -- of people that you
23 say should have access to MAT?

24 A. Yes. That -- that would be

1 inclusive.

2 Q. Okay. So it's not -- I
3 forget what the numbers are. But if
4 it's -- it -- it's not -- you don't take
5 the numbers from Section C.3 and then add
6 additional numbers for those other
7 populations?

8 MS. RELKIN: Objection to
9 form.

10 THE WITNESS: I don't
11 believe I did that in the report.

12 BY MS. WINNER:

13 Q. Okay. I just want to make
14 sure that that's not what you're
15 suggesting. Okay.

16 MS. DO AMARAL: And,
17 Counsel, just so you know, we have
18 copies of that document whenever
19 you're ready.

20 MS. WINNER: Okay. Great.
21 Thanks.

22 BY MS. WINNER:

23 Q. I was just handed the copies
24 that counsel was so kind to make for

1 Exhibit 14. Do you know what Exhibit 14
2 is?

3 A. Exhibit 14 is what we're
4 looking at?

5 Q. Yes.

6 A. So what this is is a report
7 from Suboxone pilot agencies and AOB
8 agencies that evaluates MAT.

9 Q. You say it's a report, what
10 makes you say it's a report?

11 MS. RELKIN: Objection to
12 form.

13 THE WITNESS: I suppose
14 because it provides information to
15 a group.

16 BY MS. WINNER:

17 Q. Would you agree with me that
18 this looks like a set of PowerPoint
19 slides?

20 A. There are also tables as
21 well.

22 Q. Do you know who actually
23 authored this document?

24 A. I assume that it was the

1 individuals involved in these agencies.

2 Q. But you don't know?

3 A. There is not a list of
4 authors.

5 Q. Was -- did anybody tell you
6 anything about this document when they
7 gave it to you?

8 A. It -- it was provided to me
9 based on the informational requests that
10 I made.

11 Q. To counsel?

12 A. To counsel.

13 Q. And -- so you don't know
14 anything about what the -- other than
15 what you read in this document, you don't
16 know anything that would allow you to
17 evaluate the accuracy or the reliability
18 of the data?

19 A. I think what I tried to do
20 in the report is to provide an overall
21 sense of the burden of the -- of the
22 opioid epidemic in these counties with
23 the information that I had available to
24 me, and I tried to convey the level of

1 need that there was in the counties,
2 based on the information that I had.

3 If -- if there's additional
4 information that can shed light on the
5 burden of the overdose crisis in these
6 counties, then, you know, I'd be happy to
7 consider it.

8 Q. So if the -- if the number
9 that you derived from Exhibit 13 --
10 Exhibit 14 is wrong, you would adjust the
11 calculation that you based on it?

12 A. I'm always open to new
13 information and better information if it
14 comes to light.

15 Q. Let's talk a little bit
16 about what you said -- what -- your
17 section on jail populations.

18 And that's C.4.1, correct,
19 of your report, starting on Page 34?

20 A. Yes.

21 Q. And it says, the first
22 sentence says, "Individuals in jails and
23 prisons are more likely to have" -- is
24 the word "to" missing?

1 A. Yes.

2 Q. Okay.

3 -- "more likely to have
4 opioid use disorders than individuals in
5 the general population by a factor of at
6 least 15 to 1."

7 Where does this 15 to 1 come
8 from?

9 A. So we can pull out
10 References 58 and 59.

11 Q. Okay. I'll show you 58.
12 We'll mark 58. I'm going to tell you --
13 okay. I think this is 58.

14 (Document marked for
15 identification as Exhibit
16 Keyes-15.)

17 BY MS. WINNER:

18 Q. I would like to show you
19 what's been marked as Exhibit 15.
20 "Assessing Need for Medication-Assisted
21 Treatment For Opiate-Dependent Prison
22 Inmates."

23 There's two copies there, I
24 think.

1 Is this your Reference 58?

2 A. Yes, it is.

3 Q. And is this a study that was
4 done in Puerto Rico, evaluating needs
5 assessment for the Department of
6 Corrections and Rehabilitation in Puerto
7 Rico?

8 A. So this study was used to
9 guide planning for an expansion of drug
10 treatment services in correctional
11 facilities, and need -- and it was a
12 needs assessment conducted at the
13 Department of Correction and
14 Rehabilitation of Puerto Rico.

15 Q. I think that's what I just
16 said.

17 A. I just wanted to confirm.

18 Q. Okay. And there is no
19 analysis or data in this study -- there
20 is no analysis of data in this study
21 taken from any place other than Puerto
22 Rico, is there?

23 A. In the results section of
24 this study? The -- the study was

1 conducted in Puerto Rico.

2 Q. Evaluating data gathered in
3 Puerto Rico, correct?

4 A. If I can just confirm that.
5 So the population for the study consisted
6 of 10,849 sentenced inmates midyear 2004,
7 determined from statistical data provided
8 by the DCR. So, yes.

9 Q. Now, did -- did you do any
10 evaluation to determine whether the
11 population that was evaluated in Puerto
12 Rico could be appropriated --
13 appropriately extrapolated to the jail
14 populations in Summit and Cuyahoga
15 County --

16 A. So I cited --

17 Q. Let me just --

18 A. I'm sorry, you should --
19 yes, finish your question.

20 Q. So we'll talk about the
21 other -- your other citation in a minute.

22 But did you do any
23 evaluation to determine whether the study
24 from Puerto Rico could be proper --

1 appropriately extrapolated to the jail
2 populations in Summit and Cuyahoga
3 Counties?

4 MS. RELKIN: Objection to
5 form. You can answer.

6 THE WITNESS: So, similar to
7 other sections in this report, I
8 cited the available data I had on
9 the overall population level
10 research.

11 You know, it didn't state
12 that this is the -- necessarily
13 the factor in those specific
14 counties, per se, in that
15 particular sentence.

16 I cited this study, as well
17 as another one, in order to make
18 that overall assessment of the
19 broader literature.

20 BY MS. WINNER:

21 Q. Do you know -- and I don't
22 want to take the time going through your
23 Reference 59. That's on me. I don't
24 think that 15 to 1 ratio is in there. It

1 either it is or it isn't. But did you --
2 is there any other source that you relied
3 on for this 15 to 1 ratio, other than
4 those two sources?

5 MS. RELKIN: Objection to
6 form.

7 THE WITNESS: Can I just
8 review Reference 59?

9 BY MS. WINNER:

10 Q. I don't want to take the
11 time to do that. I'm asking you, is
12 there anything that you relied on other
13 than 58 and 59?

14 A. So I just want to point out
15 that Reference 59 is not -- includes a
16 broader review of the literature. And so
17 there are other references in reference
18 59. So there's the Puerto Rico study and
19 this study, which is a special
20 communication which is not an original
21 investigation. So it encompasses -- I
22 would need to read it more carefully.
23 But it encompasses a broader range of
24 data sources.

1 Q. Did you obtain access to any
2 data about the incidence of opioid use
3 disorder specifically in the jails in
4 Summit or Cuyahoga?

5 A. I did not have access to
6 that information.

7 Q. Did you -- do you know what
8 treatment services have actually been
9 made available to inmates in those jails?

10 A. I don't think I expressed an
11 opinion about treatment services and
12 whether or not they were available. My
13 point in Section C.4.2 of the report is
14 that I can infer MAT sources from being
15 high demand, not what the current level
16 of access would be.

17 Q. Do you believe that the --
18 that there are benefits of providing
19 treatment services to inmates who have
20 opioid use disorder?

21 A. Do I believe there are
22 benefits of providing treatments -- yes.
23 I believe that there are benefits.

24 Q. Do you believe that there

1 have likely been inmates with opioid use
2 disorder in Cuyahoga County jails before
3 today?

4 A. I don't want to speculate
5 about data that I don't have access to.

6 Q. Well, is your 15 to 1 ratio
7 that you offer, is that something that's
8 a 2019 number? Or is that something that
9 you think has at least some applicability
10 generally going back in time?

11 A. So the Puerto Rico study
12 that you mentioned, the data collection
13 was in 2004. And for the citations that
14 are in this special communication, I
15 would need to look at the specific
16 references to tell you what year the data
17 were collected.

18 Q. Do you believe that
19 opioid -- excuse me. Do you believe that
20 inmates with opioid use disorder should
21 have had access to treatment?

22 MS. RELKIN: Objection to
23 form.

24 BY MS. WINNER:

1 Q. Before today?

2 MS. RELKIN: Objection.

3 Beyond her scope.

4 THE WITNESS: That's -- I'm
5 not evaluating the actual receipt
6 of services. The opinions that I
7 have in Section C.4.2 is my
8 estimate based on my review of the
9 literature, is that there would be
10 a high need for services.

11 BY MS. WINNER:

12 Q. Turning then to your
13 discussion of pregnant women. And we
14 don't have a lot of time to talk. So I
15 just have a few questions about that.

16 And do you know what MAT
17 resources are currently available in
18 Summit County for pregnant women?

19 A. So again what I did in the
20 scope of this report is to estimate, you
21 know, the potential need for services,
22 rather than what services are actually
23 available.

24 Q. And would the same -- would

1 you give me the same answer if I asked
2 you about Cuyahoga County?

3 A. So, I mean in my report is
4 what the information that was available
5 to me is, which is the number of infants
6 diagnosed with neonatal abstinence
7 syndrome and what I can infer from that
8 is that, you know, at a minimum there's
9 137 women in Cuyahoga who would be in
10 need of services in their pregnancies,
11 noting that it's probably an
12 underestimate.

13 Q. Few quick questions about
14 the child welfare system section which is
15 C.4.3 on Page 35.

16 (Document marked for
17 identification as Exhibit
18 Keyes-16.)

19 BY MS. WINNER:

20 Q. I'd like to show you what we
21 marked as Exhibit 16 to your deposition.
22 Sorry, I'm not very good at tossing
23 exhibits.

24 MS. DO AMARAL: Counsel,

1 just before you move on,
2 Exhibit 15 has some highlighting
3 in it. Is there any significance
4 to that?

5 MS. WINNER: I have no idea.

6 MS. DO AMARAL: Okay. Just
7 checking. It's just not something
8 that we discussed.

9 MS. WINNER: No, we did not.
10 And it --

11 MS. DO AMARAL: No problem.

12 MS. WINNER: Thank you.

13 BY MS. WINNER:

14 Q. First sentence of C.4.3 in
15 your report says that an estimated
16 442,995 children were in the foster care
17 system in the U.S. as of 2017. And of
18 the 269,690 who entered the system in
19 2017, 39.3 percent of those cases were
20 due to parental substance abuse disorder.
21 And then you cite Reference 171.

22 A. Yes.

23 Q. And is that --

24 MS. WINNER: What exhibit

1 number is this?

2 BY MS. WINNER:

3 Q. Is that Exhibit 16? Is that
4 the reference --

5 A. Exhibit 16 is Reference 171.

6 Q. Okay. And can you tell me
7 where that 39.3 percent figure is to be
8 found in this exhibit?

9 A. So if you look at the second
10 page -- oh, wait. So this is entering
11 the Foster care system as of 2017. So in
12 2017, drug abuse of the parent was
13 36 percent of the circumstances for the
14 child's removal. 2 percent was the drug
15 abuse of the child. Oh, but I have here
16 parental.

17 Q. Yes.

18 A. My apologies. And is 2016
19 here as well? I can provide you with an
20 updated citation that would include 2016.
21 I'm assuming that I averaged the two.
22 But --

23 Q. All right. If you would --

24 A. -- 36 is, you know, close.

1 Q. Turn to Page 36 where you
2 provide specific discussion of Cuyahoga
3 and Summit Counties in Section F.4.4.

4 Do you see that?

5 A. Yes.

6 Q. And you provide a statistics
7 in the first sentence for Cuyahoga
8 County. You then again -- you again
9 refer to Reference 171.

10 Do you see that?

11 A. I do see that.

12 Q. And can you tell me where
13 the Cuyahoga County numbers are in
14 Exhibit 171 -- in Reference 171,
15 Exhibit 16?

16 A. That might be a typo. And
17 we can provide you with an updated
18 reference. I would have to go back and
19 look at the footnotes. I mean, it's not
20 in what you provided to me here.

21 Q. And if you look at the first
22 sentence on the paragraph, next paragraph
23 on Summit County. It again -- it
24 provides a number for Summit County, and

1 again cites the same reference, correct?

2 A. We can provide you with an
3 updated citation, because I agree with
4 you it's not here.

5 Q. Okay.

6 A. We were able to provide
7 those numbers, so we can update that.

8 Q. On your opinions -- again,
9 I'm running out of time. Let me just ask
10 this real fast, about -- you also provide
11 some numbers about naloxone needs and
12 fentanyl test strips.

13 My single question about
14 both of those is, am I correct that,
15 again, you're only attempting to identify
16 needs and not evaluating what is
17 currently available in the counties for
18 these things?

19 A. So in neither section do
20 I -- I don't think I spoke to the current
21 availabilities in the counties. It was
22 really an assessment of the public health
23 need in the counties.

24 MS. WINNER: Let's go off

1 the record.

2 THE VIDEOGRAPHER: All
3 right. The time is 5:18 p.m. Off
4 the record.

5 (Short break.)

6 THE VIDEOGRAPHER: The time
7 is 5:22 p.m. Back on the record.

8 - - -

9 EXAMINATION

10 - - -

11 BY MR. O'CONNOR:

12 Q. Professor Keyes, I'm Andrew
13 O'Connor, I represent one of the
14 manufacturers in the case. I'm going to
15 be asking you some questions on their
16 behalf.

17 In connection with preparing
18 your report, did you review any marketing
19 material used by opioid manufacturers?

20 A. So, I reviewed what is cited
21 in my report. This includes a number of
22 different papers in the peer-reviewed
23 literature that go over the marketing
24 materials from --

1 Q. Other than what you've cited
2 in the report, did you review any
3 marketing materials or studies --

4 A. Everything that I reviewed
5 has been provided. I'm familiar, as part
6 of my expertise in opioid use disorders,
7 more broadly with marketing materials
8 that were used.

9 Q. And what marketing materials
10 are you familiar with through that
11 experience?

12 A. The only market -- the only
13 materials that I cite in the report that
14 I rely on for the opinions that I made,
15 are the materials that are evaluated in
16 the peer-reviewed literature, that
17 overview the -- the evidence that was
18 used to market prescription --

19 Q. Are you relying on any other
20 peer-reviewed materials other than what
21 you've cited in the report?

22 MS. RELKIN: For that
23 opinion?

24 BY MR. O'CONNOR:

1 Q. For that point?

2 A. I'm -- I'm not -- I just --
3 I'm sorry, I just want to understand the
4 question. Am I relying on any other
5 peer-reviewed materials for which --
6 which point specifically?

7 Q. For -- for any opinion on
8 marketing use -- marketing materials used
9 by opioid manufacturers.

10 A. I'm relying on the material
11 the -- to form the opinions, the material
12 that I relied on is the material that is
13 cited in this report.

14 Q. Okay. So just to be clear,
15 did you review any of the actual primary
16 source material, which is to say, the
17 material -- the marketing materials
18 themselves in writing your report?

19 A. So the --

20 MS. RELKIN: Objection to
21 form.

22 THE WITNESS: -- material
23 that I relied on to write my
24 report included a broad range of

1 peer-reviewed literature, articles
2 that evaluate evidence that was
3 used in marketing materials.

4 More broadly, given 15 years
5 of studying opioid use disorders,
6 I'm familiar with marketing
7 materials that were used. There
8 was no marketing material that I
9 relied on to form the opinion that
10 is in this report.

11 BY MR. O'CONNOR:

12 Q. In 15 years what marketing
13 materials related to pharmaceutical
14 opioids did you review?

15 A. There has been voluminous
16 evidence, as I cite here, regarding
17 distribution, sales and marketing of
18 opioids.

19 Q. Does any of the evidence
20 you're referring to relate to any
21 manufacturing defendants in this case?

22 MS. RELKIN: Objection to
23 form.

24 You mean specific? Is that

1 what you said?

2 THE WITNESS: Does any of
3 the evidence that I'm referring to
4 relate to any manufacturing -- I
5 think the evidence that I've
6 provided in this report relates to
7 manufacturers of opioids.

8 BY MR. O'CONNOR:

9 Q. Professor Keyes, who are the
10 manufacturing defendants in this case?

11 A. There's a broad range of
12 manufacturing defendants in the case.
13 You know, I'm not -- I know that Purdue,
14 Janssen, Teva, a number of other
15 manufacturers are involved.

16 Q. Can you name any other
17 manufacturers as you sit here today?

18 A. I would have to go back to
19 my materials. You know, I think it's all
20 cited in the complaint. The -- the
21 opinions that I derived at for this
22 report are not specific to any particular
23 manufacturer unless I cite a specific
24 product in the report. So all of the

1 opinions that I've arrived at are about
2 the overall emergence of an opioid
3 epidemic in the United States.

4 Q. In connection with Purdue,
5 did you review any Purdue marketing
6 materials yourself?

7 A. In connection with Purdue?
8 So what I've cited -- I -- I think I've
9 answered the question. What I've cited
10 in the -- in the report is the
11 peer-reviewed literature that evaluates
12 the evidence that was used for marketing
13 materials.

14 Q. I'm going to mark an exhibit
15 that you cite in your report.

16 (Document marked for
17 identification as Exhibit
18 Keyes-17.)

19 BY MR. O'CONNOR:

20 Q. It's a study by Art Van Zee.
21 It's marked Exhibit 17.

22 A. Can you tell me which
23 citation number it is in the report?

24 Q. I believe it's 15.

1 Do you know who Art Van Zee
2 is?

3 A. Sorry, I'm just trying to
4 find the specific place I reference that.
5 Do you know what page it's on?

6 So I -- the use of that
7 article is for the statement, "From 1997
8 to 2002, prescriptions for OxyContin for
9 noncancer pain increased from
10 approximately 670,000 in 1997 to" -- "to
11 about 6.2 million in 2002. Prescriptions
12 for cancer pain also increased about
13 fourfold across the same period."

14 Q. Back to my question. Do you
15 know who Art Van Zee is?

16 A. Do I know him personally?

17 Q. Do you know who -- who he is
18 generally?

19 A. According to the article, he
20 is an M.D., and he is affiliated with
21 Stone Mountain Health Services.

22 Q. Other than what you're
23 reading right now, are you familiar with
24 his credentials?

1 A. I'm not aware of other
2 articles by Art Van Zee that I relied on
3 for the opinions in this report.

4 Q. To your knowledge, is he an
5 epidemiologist?

6 A. I have not evaluated his
7 training.

8 Q. Does he have any expertise
9 related to the marketing of prescription
10 opioids?

11 MS. RELKIN: Objection.

12 THE WITNESS: That's not
13 information that was -- I think
14 the statement in the -- where I
15 cite his work is based on what is
16 written here. I don't think it --

17 I'm sorry, your question
18 was: Do I have any knowledge of
19 his expertise related to the
20 marketing of prescription opioids?
21 I'm not sure how that relates to
22 the statement that "OxyContin for
23 noncancer pain increased from
24 approximately 670,000 to

1 6.2 million."

2 BY MR. O'CONNOR:

3 Q. Okay. Let's look at a
4 different portion of your report. On
5 Page 11 near the top you discuss direct
6 marketing to physicians using the data
7 that underestimated opioid use disorder
8 risks in patients.

9 What direct marketing to
10 physicians were you referring to in that
11 statement in your report?

12 A. I was citing the evidence
13 that is in the peer-reviewed journal that
14 the studies on opioid use disorder risk
15 among noncancer pain patients
16 underestimated risk.

17 Q. And which studies -- or
18 which marketing materials, rather, are
19 cited in those materials?

20 A. So there are a number of
21 studies that have looked at marketing --
22 marketing and other materials as -- as
23 part of the assessment of the overall
24 burden of the emergence of the epidemic

1 that I cited in my peer-reviewed
2 literature.

3 Q. How did --

4 A. In an epidemiologic report,
5 you know, we rely on the -- on the
6 evidence based on the methodology that I
7 cited in the beginning.

8 Q. Other than the Van Zee
9 paper, can you point me to any other
10 papers that you cite that deal with
11 whether marketing materials used with
12 physicians underestimated the risks of
13 opioids?

14 A. Sure. I would point to the
15 Hadland article.

16 Q. Okay.

17 A. Let me find that for you.

18 Q. I think I can help you out.

19 A. Do you have a copy --

20 Q. Well, first, which Hadland
21 article? There are a few I believe.

22 A. So on Page 22, I cite
23 Reference 15. I'll just pull that up.

24 So that's the Van Zee article in talking

1 about -- that the risk of disorder, harm,
2 and diversion was underestimated.

3 Q. That's your Citation 15?

4 A. That's my Citation 15.

5 Q. And that -- that's just one
6 article, right, the Van Zee article?

7 A. And so -- right. And so
8 then Reference 17, "Pharmaceutical
9 Company Marketing to Physicians is
10 Extensive in the United States." That's
11 based on DeJong et al., 2016. Would you
12 like to go over that one?

13 Q. No, I just want to --

14 A. Do you want to go to
15 Hadland?

16 Q. I want to focus just for
17 another moment on the Van Zee, since
18 that's the only one that's cited for the
19 proposition --

20 A. No, no, that's not the only
21 one that's cited.

22 Q. I'm sorry. Is there another
23 one that's cited for the proposition that
24 sources underestimated the risk of opioid

1 use disorder?

2 A. That's an introductory
3 sentence for a whole paragraph of
4 evidence, the summation of which support
5 the statement. So I'm not relying on any
6 one particular source.

7 Q. Okay. In Footnote 15, you
8 cite Van Zee. That study relates only to
9 the marketing of OxyContin, correct?

10 A. Again, I'm not relying on
11 that source solely to provide all of the
12 evidence for the marketing of
13 pharmaceuticals and the underestimation
14 of risk. I will agree with you that this
15 particular paper focuses on the promotion
16 and marketing of OxyContin. But there
17 are other studies that I relied on.

18 Q. Okay. Thank you. When you
19 say other studies, are you referring to
20 Hadland?

21 A. I'm referring to the other
22 studies in this paragraph. There may be
23 other studies in the report as well. But
24 we can focus on these to start.

1 Q. So let me show you what's
2 marked as Exhibit 18, which is an article
3 by Hadland.

4 (Document marked for
5 identification as Exhibit
6 Keyes-18.)

7 BY MR. O'CONNOR:

8 Q. Called "Association of
9 Pharmaceutical Industry Marketing of
10 Opioid Products to Physicians With
11 Subsequent Opioid Prescribing"?

12 A. So I just want to confirm
13 that this is the correct citation.

14 Yes.

15 Q. Did you review this article
16 by Dr. Hadland before you cited it in
17 your report?

18 A. What do you mean by
19 "review"?

20 Q. Did you read the study
21 before you cited it in your report?

22 A. I read the study.

23 Q. And you made the decision to
24 cite it, correct?

1 A. That's correct.

2 Q. Okay. I'd like to direct
3 your attention to the first sentence of
4 the first paragraph -- I'm sorry, the
5 second paragraph. It says,
6 "Pharmaceutical industry marketing to
7 physicians is widespread, but it is
8 unclear whether the marketing of opioids
9 influences prescribing."

10 Do you agree with that
11 statement?

12 A. So I believe that's the
13 topic of the paper.

14 Q. Do you agree with that
15 statement?

16 A. I would agree that that
17 statement was used to set up the
18 rationale for the analysis that we are
19 looking at. So I -- that is the topic
20 that the investigators sought to
21 investigate in their studies. So
22 abstracting that one sentence is an
23 inaccurate representation of what the
24 findings of the study were.

1 Q. So I'm sorry. Do you agree
2 or disagree with that statement?

3 MS. RELKIN: Objection.

4 Asked and answered.

5 THE WITNESS: I've answered
6 the question. That --

7 BY MR. O'CONNOR:

8 Q. I've asked it. You haven't
9 answered it.

10 A. So in a scientific paper
11 when you write an introduction, the way
12 you set it up is to assess, you know,
13 what's known in the literature, what some
14 gaps in the literature are.

15 This particular sentence is
16 setting up what is the analysis that was
17 done.

18 He also cites in that paper
19 another paper, "Industry Payments to
20 Physicians For Opioid Products 2013 to
21 2015" which I think also provides
22 evidence.

23 Q. Okay. Can you show me in
24 this article where, if anywhere, it

1 suggest that the risks of opioids were
2 understated?

3 A. That is not the purpose of
4 this article. I have reviewed a
5 different body of evidence to support
6 that opinion.

7 Q. Okay. And what body of
8 evidence is that?

9 A. That is in Section B.2.

10 Q. Does -- Section B.2 deals
11 with your assessment of the risks of
12 opioids, correct?

13 A. Section B.2 is a review of
14 the literature on opioid use disorder and
15 related consequences among medical users
16 of opioids.

17 Q. But B.2 is -- does not deal
18 with what opioid manufacturers said in
19 their marketing materials, does it?

20 A. That is cited in other work.

21 Q. Okay. Because what you just
22 said -- go to B.2. And now where should
23 I go to find the section that says --

24 A. You're making two different

1 statements.

2 MS. RELKIN: Objection to
3 form.

4 BY MR. O'CONNOR:

5 Q. What I'm asking is simply,
6 direct me to the part of the report that
7 provides support for the statement that
8 opioid marketing materials understated
9 the risks of opioids.

10 A. So I would say that there's
11 two different sections that evaluate that
12 statement. One is Section B.2. And in
13 section B.2, I provide an overview of a
14 number of different studies that have
15 estimated opioid use disorder and related
16 consequences among medical users of
17 opioids.

18 And then in several other
19 sections of the report, I also cite the
20 peer-reviewed literature on the
21 association between the marketing of
22 opioid products with risk.

23 Q. Okay. I'd like to direct
24 your attention to Page 11 of your report,

1 which we were just looking at a moment
2 ago.

3 You state that evidence
4 shows that pharmaceutical marketing of
5 prescription drugs increases prescribers'
6 likelihood of prescribing the marketed
7 drug in the future.

8 A. I just need to find that
9 section.

10 Q. It's near the top. The last
11 sentence --

12 A. "Evidence shows that
13 pharmaceutical marketing of prescription
14 drugs increases the prescribers
15 likelihood of prescribing."

16 Q. And you cite Sources 16 and
17 17.

18 And 16 is a study by
19 Dr. Fickweiler. Did I get that right?

20 A. Yes.

21 Q. Did you read the study by
22 Dr. Fickweiler before you cited it?

23 A. I'm just going to pull the
24 study out.

1 (Document marked for
2 identification as Exhibit
3 Keyes-19.)

4 BY MR. O'CONNOR:

5 Q. Here. I've marked it as
6 Exhibit 19.

7 A. Okay. So this is a study --
8 this is a review study. It looks at the
9 interaction between physicians and
10 pharmaceutical industry, including sales
11 representatives, on their impact on
12 physicians attitudes and prescribing
13 habits.

14 Q. Okay. And you cited this
15 study in connection with your statement
16 on Page 11?

17 A. Yes.

18 Q. I'll direct your attention
19 to the second line of the second column.
20 It says, "However, the evidence
21 determining whether pharmaceutical
22 industry and PSRs'," which here means
23 pharmaceutical sales representatives,
24 "interaction influence physicians is

1 divided and contradictory."

2 Do you agree that the
3 evidence determining whether
4 pharmaceutical industry interactions
5 influence physicians, is, quote, "divided
6 and contradictory"?

7 MS. RELKIN: Objection to
8 form.

9 THE WITNESS: Again, this is
10 an introduction of a scientific
11 paper. The purpose of an
12 introduction is to set up what's
13 known, not known, and the gaps in
14 the literature.

15 So that's not the conclusion
16 or the results of this analysis.
17 So I cited it in the paper, in my
18 report, based on its results, and
19 not for a statement in the
20 introduction that's setting up why
21 the study was conducted.

22 BY MR. O'CONNOR:

23 Q. So would you agree that as
24 of the writing of this introduction that

1 the evidence determining whether
2 pharmaceutical industry interactions
3 influence physicians was divided and
4 contradictory?

5 A. I would need to look at the
6 specific citation, 17, 18, 19 through 22
7 and 23 through 26 to make a designation
8 about whether or not I agree with that
9 particular characterization. It's
10 typically -- it's typical in the
11 scientific literature that we set up what
12 the gaps in the literature are. And so
13 these studies would need to be looked at
14 one by one.

15 Q. Did this -- did this study
16 by Dr. Fickweiler resolve any divided and
17 contradictory evidence on this question?

18 MS. RELKIN: Objection to
19 form.

20 THE WITNESS: So I believe
21 it's cited both this study and
22 another study with respect to that
23 statement. I'm sorry. I can't
24 find it.

1 What this paper evaluated is
2 an entire review of the
3 literature. So it provides a
4 synthesis of those gaps and
5 limitations.

6 BY MR. O'CONNOR:

7 Q. Okay. And this study was
8 in -- was published in 2017, correct?

9 A. Yes, it was published in
10 2017.

11 Q. If you go back to
12 Exhibit 18, which is the Hadland article.

13 A. Oh sorry. This is the
14 Hadland.

15 MS. RELKIN: One of the
16 Hadland.

17 BY MR. O'CONNOR:

18 Q. One of the Hadland articles.
19 The one that we looked at earlier. This
20 was published in June of 2018, the next
21 year, correct?

22 A. Both of these, yes. It was
23 published in 2018.

24 Q. And at this point, at least

1 according to the introduction, it was
2 still unclear whether marketing of
3 opioids influenced prescribing, correct?

4 MS. RELKIN: Objection to
5 form.

6 THE WITNESS: I -- I feel
7 that I've answered the question.
8 This is a -- what's standardly
9 done in introduction to scientific
10 papers is a setup of the actual
11 results that were going to be
12 presented in the papers. In order
13 to determine what the actual
14 strength of the evidence is for
15 pharmaceutical marketing of
16 opioids and whether it influenced
17 prescribing, we would need to go
18 into each one of these studies. I
19 wouldn't -- I don't think you can
20 make a generalization about what's
21 known in the world or to whom,
22 based on one sentence in an
23 introduction section.

24 BY MR. O'CONNOR:

1 Q. In connection with preparing
2 your report, did you examine what factors
3 influence physicians' prescribing
4 decisions?

5 MS. RELKIN: Objection.

6 THE WITNESS: Did I examine
7 what factors influence physicians'
8 prescribing decisions? I believe
9 I've cited a number of studies
10 with respect to that question in
11 this report.

12 BY MR. O'CONNOR:

13 Q. Which studies are those?

14 A. The studies that are in
15 front of you are among them.

16 Q. Any others come to mind that
17 go to that point?

18 A. Yeah, there are a number of
19 studies that are in Section B.2 that also
20 evaluate different aspects of -- again, I
21 look at aggregate level data. And so
22 there are a number of studies in B.2 that
23 look at different risk metrics for how
24 physicians prescribe.

1 Q. Fair to say you didn't
2 consider any studies outside of the ones
3 cited in your report, correct?

4 A. I believe you've been
5 provided with all the material that I
6 evaluated to make my opinions.

7 Q. Okay. In considering -- or
8 in writing your report, did you consider
9 whether -- what physicians learn in
10 medical school impacts their prescribing
11 decision with respect to opioids?

12 A. Where physicians were in
13 medical school or what --

14 Q. Did you consider whether
15 what physicians learned in medical school
16 impacted their decisions to write
17 opioids?

18 A. So I do epidemiological
19 literature review and data analysis. It
20 is at a population level. And the
21 population level data indicates that
22 often what physicians were told, they
23 were misinformed about the risks and
24 benefits of opioids.

1 Q. And were they -- who were
2 they told by?

3 A. The available literature
4 that I have cited in this report points
5 to materials that were received by the
6 manufacturers.

7 Q. Okay. And so in forming
8 your opinion, you didn't consider what
9 physicians learned in medical school, did
10 you?

11 A. People that teach in medical
12 school are also physicians. So they
13 are -- they are not developing their --
14 what they teach de novo.

15 Q. And in forming your opinion,
16 you didn't consider whether formularies
17 or third-party payor guidelines could
18 affect physicians' prescribing decisions,
19 did you?

20 MS. RELKIN: Objection to
21 form.

22 THE WITNESS: Can you give
23 me an example of formularies and
24 third-party payor guidelines?

1 BY MR. O'CONNOR:

2 Q. Well, did you consider the
3 extent to which whether a prescription is
4 covered by an insurance company would
5 affect a physician's prescribing
6 decisions?

7 A. Again, I'm looking at
8 aggregate data with respect to individual
9 level and population level factors that
10 influence variation and risk. So whether
11 or not a prescription is covered by an
12 insurance company, whether that affects
13 the physician's decision is going to be
14 dependent on a lot of factors. And
15 doesn't change what's in the published
16 literature regarding the misinformation
17 on the risks of opioids.

18 Q. And that literature you're
19 referring to doesn't take into account
20 the question of formulary coverage, does
21 it?

22 A. Your question is whether
23 every single one of these papers takes
24 into account the question of formulary

1 coverage?

2 Q. Does any of them?

3 A. That's a question about
4 confounding. And so in order to evaluate
5 whether formulary coverage is
6 confounding, the estimates that are in
7 this study, we would need to look at the
8 definition of confounding, which I've
9 provided in the report.

10 Q. And none of those studies
11 that are sitting in front of you address
12 this question of whether something like
13 formulary coverage influences prescribing
14 decisions, correct?

15 A. I would need to look at the
16 studies.

17 MR. O'CONNOR: Let's go
18 ahead and take a break.

19 THE VIDEOGRAPHER: The time
20 is 5:47 p.m. Off the record.

21 (Short break.)

22 THE VIDEOGRAPHER: We are
23 back on the record. The time is
24 5:53 p.m.

1 BY MR. O'CONNOR:

2 Q. Professor Keyes, I'm going
3 to direct you to Page 20 of your report.
4 In the first sentence of the last
5 paragraph, it says, "There have been
6 rapid increases in opioid overdose death
7 due to heroin and synthetic opioids."

8 When you say synthetic
9 opioids, does that include fentanyl?

10 A. Yes.

11 Q. And when you talk about
12 fentanyl in your report, does that mean
13 legally manufactured fentanyl or
14 illegally manufactured fentanyl?

15 MS. RELKIN: Objection to
16 form.

17 THE WITNESS: So the
18 specific data that I cite is
19 regarding the overdose deaths
20 based on the T codes. And I don't
21 think there's a separation between
22 illegal and legal.

23 BY MR. O'CONNOR:

24 Q. So when we see fentanyl in

1 the report, it's not distinguishing
2 between legally manufactured fentanyl and
3 illegally manufactured fentanyl?

4 A. It depends on the statement.
5 I don't want to make a blanket statement
6 about the report.

7 Q. With respect to opioid
8 overdose deaths, as you sit here today,
9 do you know which proportion of those
10 that involve fentanyl involved illicitly
11 made fentanyl versus legally manufactured
12 fentanyl?

13 A. So you're asking a question
14 about Reference 64 I believe. And
15 Reference 64 -- let me check my source --
16 is, yes, the Hedegaard -- the CDC report
17 on drug overdose deaths in the United
18 States from 1999 to 2017. Those data
19 report the -- the T codes that are
20 designated on the death certificate for
21 each death. And those do not separate
22 out illegal from legal.

23 Q. And with respect to opioid
24 overdose deaths generally, outside the

1 context of that one article, are you
2 familiar with the proportion of deaths
3 that are attributable to illegally
4 manufactured fentanyl?

5 A. The available data on opioid
6 overdose deaths in the United States are
7 largely drawn from the National Vital
8 Statistics Service, which provides the
9 most reliable information on death
10 certificates and does not designate
11 between those two.

12 Q. And so there is no way from
13 that information to distinguish between
14 legally made and illegally made fentanyl,
15 correct?

16 A. Not based on the death
17 records, no.

18 MR. O'CONNOR: All right.
19 That's all I have.

20 But for the reasons my
21 colleague stated earlier, we're
22 reserving our right to keep this
23 deposition open and to continue it
24 or move to strike the witness

1 because of our inability to ask
2 other questions we wanted to,
3 given the answers the witness
4 provided today.

5 MS. DO AMARAL: You have two
6 minutes. If you've got any
7 questions, ask them now.

8 MR. CIACCIO: If you have
9 any questions, ask it, you have
10 two minutes.

11 MR. O'CONNOR: I'll ask two
12 minutes of questions.

13 BY MR. O'CONNOR:

14 Q. So are you familiar with
15 generic opioids?

16 A. What do you mean by
17 familiar?

18 Q. Do you know the difference
19 between branded opioids and generic
20 opioids?

21 A. The -- the literature that I
22 assessed in this report is on the overall
23 opioid epidemic. When there was a
24 specific opioid that was mentioned in

1 that literature, I -- I've cited it in
2 this report.

3 Q. Do you know that generic
4 opioids aren't promoted to doctors in the
5 same way that branded opioids are?

6 A. I would need to see the
7 documentation. That's not something that
8 was covered in my report. So I would not
9 agree with the statement that I had not
10 evaluated the literature on.

11 Q. Well, if that statement were
12 true, would it change your opinions about
13 whether manufacturers of those products
14 contributed to opioid prescribing?

15 MS. RELKIN: Objection to
16 form.

17 THE WITNESS: I -- what I
18 did in this report is an overview
19 of the literature on what is known
20 about the emergence of the opioid
21 epidemic. I would always keep an
22 open mind to new information. But
23 you have not given me any
24 information with which to evaluate

1 whether my mind would be changed
2 or not based on that information.

3 BY MR. O'CONNOR:

4 Q. Well, I'm asking you to
5 assume that a particular product was not
6 promoted to physicians.

7 A. That's -- the -- that
8 assumption is not what happened. So I
9 evaluated what happened.

10 Q. Well, I think you said a
11 moment ago you were open to learning new
12 information. And I -- I'm saying, if you
13 learned that a particular product was not
14 promoted to doctors, would that change
15 your opinion?

16 MS. RELKIN: Objection.

17 THE WITNESS: I -- I am not
18 agreeing with that assumption,
19 based on the literature that I
20 reviewed, and the literature that
21 is cited in this report. I don't
22 have any evidence with which to
23 agree with that assumption and the
24 premise of the question.

1 BY MR. O'CONNOR:

2 Q. And I understand you don't
3 agree with the assumption. But I'm
4 saying, if you learned that new
5 information you say you're open to and
6 what I said was correct, does that change
7 your opinion?

8 MS. RELKIN: Objection to
9 form.

10 THE WITNESS: I haven't
11 learned any new information.

12 MR. CIACCIO: That's two
13 minutes.

14 MR. O'CONNOR: Okay. For
15 all the reasons we already talked
16 about, we reserve our rights.
17 Thank you. Thank you for your
18 time.

19 MS. RELKIN: No questions.

20 THE VIDEOGRAPHER: Off the
21 record. Okay. The time is
22 5:58 p.m. Going off the record.

23 MR. REATEGUE: Bruno
24 Reategue, for the Teva defendants,

1 I'd like to put a due process
2 violation on the record for not
3 being able to ask questions in a
4 meaningful way. Thank you.

5 (Excused.)

6 (Deposition concluded at
7 approximately 5:58 p.m.)

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1
2 CERTIFICATE
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4

5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.

9 It was requested before
10 completion of the deposition that the
11 witness, KATHERINE KEYES, Ph.D. have the
12 opportunity to read and sign the
13 deposition transcript.

14
15 
16 _____

17 MICHELLE L. GRAY,
18 A Registered Professional
19 Reporter, Certified Shorthand
20 Reporter, Certified Realtime
21 Reporter and Notary Public
22 Dated: May 2, 2019
23
24

25 (The foregoing certification
26 of this transcript does not apply to any
27 reproduction of the same by any means,
28 unless under the direct control and/or
29 supervision of the certifying reporter.)
30

1 INSTRUCTIONS TO WITNESS

2
3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

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E R R A T A

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4 PAGE LINE CHANGE

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REASON:

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2 ACKNOWLEDGMENT OF DEPONENT
3

4 I, _____, do
5 hereby certify that I have read the
6 foregoing pages, 1 - 494, and that the
7 same is a correct transcription of the
8 answers given by me to the questions
9 therein propounded, except for the
10 corrections or changes in form or
11 substance, if any, noted in the attached
12 Errata Sheet.
13
14
15

16 _____
KATHERINE KEYES, Ph.D.

DATE

17
18
19 Subscribed and sworn
to before me this

20 _____ day of _____, 20____.

21 My commission expires: _____
22 _____

23 Notary Public
24

	LAWYER'S NOTES		
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